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## The International Right to Health: What Does It Mean in Legal Practice and How Can It Affect Priority Setting for Universal Health Coverage?

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2(1) HEALTH SYSTEMS & REFORM 23-31

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**To cite this article:** Rebecca Dittrich, Leonardo Cubillos, Lawrence Gostin, Kalipso Chalkidou & Ryan Li (2016) The International Right to Health: What Does It Mean in Legal Practice and How Can It Affect Priority Setting for Universal Health Coverage?, *Health Systems & Reform*, 2:1, 23-31, DOI: [10.1080/23288604.2016.1124167](https://doi.org/10.1080/23288604.2016.1124167)

**To link to this article:** <http://dx.doi.org/10.1080/23288604.2016.1124167>



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Published online: 21 Jan 2016.



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## Research Article

# The International Right to Health: What Does It Mean in Legal Practice and How Can It Affect Priority Setting for Universal Health Coverage?

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Keywords: health technology assessment, judicialization of right to health, priority setting, rational priority setting, right to health, universal health coverage

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Received 2 October 2015; revised 18 November 2015; accepted 20 November 2015.

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**Abstract**—The international right to health is enshrined in national and international law. In a growing number of cases, individuals denied access to high-cost medicines and technologies under universal coverage systems have turned to the courts to challenge the denial of access as against their right to health. In some instances, patients seek access to medicines, services, or technologies that they would have access to under universal coverage if not for government, health system, or service delivery shortfalls. In others, patients seek access to medicines, services, or technologies that have not been included or that have been explicitly denied for coverage due to prioritization. In the former, judicialization of the right to health is critical to ensure patients access to the technologies or services to which they are entitled. In the latter, courts may grant patients access to medicines not covered as a result of explicit priority setting to allocate finite resources. By doing so, courts may give priority to those with the means and incentive to turn to the courts, at the expense of the maximization of equity- and population-based health. Evidence-based, informed decision-making processes could ensure that the most clinically and cost-effective products aligning with social value judgments are prioritized. Governments should be equipped to engage in and defend rational priority setting, and the priority setting process and institutions involved should be held accountable through an opportunity for appeal and judicial review. As a result, the courts could place greater reliance on the government's coverage choices, and the population's health could be most equitably distributed.

## INTRODUCTION

The emergence of advanced health technologies, new pharmaceuticals and medical devices, and innovative health care

services has forced governments to make difficult prioritization decisions within a limited health care budget. With implicit priority setting, clinicians use their discretion to determine who will get what care.<sup>1</sup> Under explicit priority setting, governments can utilize formal processes to allocate resources to maximize the population health impact of universal coverage.<sup>2</sup> Sometimes these processes are successful, but other times they fail to give due consideration to financial or delivery system constraints. Rational priority setting is an evidence-based form of explicit priority setting. Priority setting is rational when the process is made explicit and transparent, the decision makers are specified, and it is conducted in a deliberative manner, involving relevant stakeholders, and in consideration of best available evidence about clinical and cost-effectiveness and social values.<sup>3</sup> The most rational priority setting processes will also account for the benefit to patients, the cost, the ethicality and the fairness. As governments make these prioritization decisions, they face another challenge: conflict with the judiciary. Individuals often turn to the court system to argue that denying public coverage of a given product contradicts their internationally or nationally guaranteed right to health. And they are often winning their cases.<sup>4</sup> Through this “judicialization” of the right to health, courts can determine that administrative inefficiencies and prioritization processes that deny an individual access to his or her desired, or required, health care service violate that government’s duty to protect the right to health.<sup>5,6</sup>

The international right to health is enshrined in major multilateral treaties and smaller human rights treaties, offering protection based on gender, race, and age.<sup>7</sup> Article 25 of the Universal Declaration of Human Rights grants “everyone . . . the right to a standard of living adequate for the health and well-being of himself and of his family, including . . . medical care and necessary social services.”<sup>8</sup> The United Nations General Assembly unanimously pronounced the contents of this Declaration to be a standard for all human beings in 1948.<sup>7</sup> The International Covenant on Economic, Social and Cultural Rights, Article 12, “recognize[s] the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>9</sup> In 2000, the Committee on Economic, Social, and Cultural Rights released General Comment 14 to explain the three right to health obligations of states: to respect, to protect, and to fulfill.<sup>10</sup> The right to health is also a key element in the World Health Organization’s Constitution, the preamble of which declares “the enjoyment of the highest attainable standard of health [to be] one of the fundamental rights of every human being. . . .”<sup>11</sup>

Many states have the right to health embedded in domestic law. Over 100 national constitutions contain the right to

health, representing over 50% of United Nations Member States from Asia and Africa to Europe and Latin America. They guarantee or aspire to protect a right to health generally, a right to public or preventive health, and/or a right to medical care services.<sup>12</sup> For example, Article 196 of the Brazilian Constitution mandates that “health is the right of all and a duty of the State and shall be guaranteed by . . . universal access to all activities and services for its promotion, protection, and recovery.”<sup>13</sup> Article 19 of the Haitian Constitution recognizes the State’s “absolute obligation to guarantee the right to life, health, and respect of the human person.”<sup>14</sup> Many states also incorporate the right to health in their domestic statutes, which gives it the force of domestic law and makes it potentially enforceable through the courts. Citizens have filed writs of protection in mass quantities to protect these rights.<sup>6</sup>

The inclusion of the right to health in a state’s constitution or statute may not even be a necessary condition for citizens to be able to bring right to health claims against priority setting. In the absence of a nationally explicit right to health guarantee, citizens turn to the international legal instruments or to claims based on a national right to life, dignity, or human integrity.<sup>15-18</sup> As a result, legal claims disputing priority setting pose a challenge to governments engaging in explicit priority setting, regardless of whether or not a right to health has been incorporated in the national constitution.

Importantly, this judicialization of the right to health is often critical for granting access to the health care products citizens are entitled to under a state’s universal coverage system—and indeed would have, if not for government failure. For example, in 1993, Colombia passed a law creating a two-tier benefit system utilizing public and private insurers to purchase health care for patients. The dramatic increase in court claims following the implementation of the reform was a sign of systemic failures in its implementation—patients consistently brought court action to demand access to services already in their coverage plans.<sup>19</sup> In such cases, the courts played a fundamental role in exposing systemic inefficiencies denying citizens access to services to which they were legally entitled. Similarly, the courts of Brazil, Costa Rica, and Argentina have handed down a number of rulings that expose the lack of enforcement of the established priorities.<sup>20</sup>

In a second type of judicialization of the right to health, patients challenge explicit and ostensibly reasonable priority-setting decisions that deny access to care—care that then sometimes is prescribed by a physician even though not in the benefits package. Thereby, courts override a government’s official priority-setting process.

Sometimes the government's decision not to include a technology in the health benefit package may have been ill-advised, and the court's granting of an individual critical access to a necessary technology may be a desirable correction. However, if the government made an informed priority-setting decision that courts nonetheless overturn, the judicialization of the right to health may threaten reasonable and responsible decisions by the government. Thus, if governments use a fair and rational process based on evidence and carefully stated value judgments, and do so via an ethically acceptable process, should the courts be enabled nonetheless to overturn those decisions?

We recognize the importance of the judicialization of the right to health, because it can be vital to ensure that governments abide by the letter and spirit of international human rights. However, rational priority setting based on evidence and with an eye to equity is, we argue, the best way to safeguard an ethical allocation of scarce health care resources, and it should be protected. We propose methods to ensure that governments engage in rational priority-setting processes and to equip courts with the tools necessary to assess whether or not rational priority setting has been conducted. With this knowledge, courts can better decide whether exclusion of a health care product truly threatens the right to health.

## THE ETHICS OF ALLOCATING RESOURCES

Priority setting confronts a critical question: how does society ethically allocate scarce resources? Patients utilizing Article 12 of the International Covenant on Economic, Social and Cultural Rights, or similar rights, in their right to health claim could argue that they have a right to their "highest attainable standard" of health, for example.<sup>9,17</sup> However, states cannot guarantee a *carte blanche* highest attainable standard of health to every citizen without consideration of resource constraints. Attempting to meet the maximal health care needs of every individual would overwhelm a society's capacity to provide other social goods, such as education and defense.<sup>21</sup> The question, then, is: what is a reasonable principle for allocating resources, and to what body is the decision maker accountable in applying such a principle?

Equity and ethics should be critical considerations to ensure proper priority setting. Governments should consider whether the interests of some groups are unfairly promoted over those of another. Attention to the principle of equity in access to care, quality of care, outcomes, and financial protection can promote a fair distribution of benefits across different population and disease groups.<sup>22</sup>

When seeking to maximize population health, the government should not disregard its ethical obligation to secure benefits for, and reduce harms to, individuals.<sup>22</sup> In some instances, attention to population-level health may disregard the individualized needs of a highly vulnerable disease group. The government may wish to develop policies to recognize and offer protections for these highly individualized needs. It is important to give particular attention to the needs of society's most vulnerable and marginalized inhabitants. Even if an intervention is not the most cost-effective, it may be necessary to ensure vulnerable disease groups an equal opportunity to their right to health. Court decisions to overturn a coverage decision may maximize individual health only for those with the resources to bring a claim but not those in vulnerable disease groups.

An equitable benefits package generally excludes health care products that cannot be provided to everyone for whom that product is medically indicated.<sup>22</sup> A court's decision to grant a patient access to the product she demands typically applies only to that patient.<sup>5</sup> Thus, decisions granting individuals access to the interventions they demand can create horizontal inequity because others having the same need for the intervention are treated differently.<sup>6</sup> If we understood the right to health strictly on an individual level the outcome is likely to be an unequal, subjective access to the highest attainable health standard. To prevent this, courts could seek to uphold priority setting decisions when they are in reasonable alignment with the evidence and the social value judgments of that broader society.<sup>21,23</sup>

The highest attainable standard of health of a citizenry can only be determined within the confines of what the country can fairly afford. This is true as long as the government is already allocating a fair percentage of its total budget to health care. By granting access to products based on an individual's right to health without carefully considering that the product may have been rationally denied, courts could secure one individual access to a product unaffordable for all who would need it. In doing so, the courts threaten the broader population right to health.<sup>24</sup>

## WHEN THE ETHICAL AND EQUITABLE ALLOCATION OF RESOURCES IS PUT AT RISK

The primary goal of a universal health coverage system is to achieve the highest level of service coverage for the population as a whole. If the government indiscriminately granted access to all products patients requested or doctors prescribed, it would risk deflecting scarce resources from low-cost, high-effectiveness, broad-impact products toward high-cost, low-potential products.

In *Marquez Velazquez Antonio Gerardo vs. Ministry of Public Health*, the Uruguayan court granted a patient access to the drug Sunitinib after Sorafenib failed to treat his metastatic kidney cancer. Sunitinib was subsequently included on the national drug form. However, the level 1 studies required by regulation to prove the drug's effectiveness subsequent to Sorafenib—and place it on the national drug form for subsequent use—had never been conducted. The court found it “manifestly illegitimate” to require proof of the effectiveness of using the treatments in sequential order, stating that it is the physician's job only to provide means, not to produce results. It states that a “high level of scientific evidence” supports the use of Sunitinib subsequent to Sorafenib, and “the only way to know whether the drug works is to give it to the patient.”<sup>25</sup> The *Gerardo* decision challenges Uruguay's efforts to set up an evidence-based system for priority setting and undermines the financial solvency of its health care system.

Some courts place greater weight on the opinion of the recommending physician than that of government-provided clinical experts or the protocol for determining coverage itself.<sup>6,26,27</sup> At times, this is due to poor representation by the government to support its method of priority setting and to challenge contradicting evidence.<sup>28</sup> However, it is often due to judicial deference to the prescribing physician. One study of relevant Brazilian court decisions between 2007 and 2008 found that 97% of cases were decided on the medical evidence provided by the prescribing physician, without considering the quality of the treatment, patient need, or alternative treatment options.<sup>27,29</sup>

Costa Rican courts frequently decided that a prescription from the prescribing physician outweighs the technical standards used to determine coverage.<sup>26</sup> In *Ms. Vera Salazar Navarro vs. Caja Costarricense de Seguro Social*, the Costa Rican Social Security Institution refused to cover the branded drug Ms. Navarro demanded for her multiple sclerosis, instead offering to reimburse the less expensive generic option. The court ordered the Institution to reimburse the branded alternative, on the basis that the Institution breached the patient's right to health by refusing to cover the exact drug the physician prescribed.<sup>15</sup> In the last three years, however, Costa Rican courts have begun to give more weight to the evidence supporting a coverage decision, signaling that they may be prepared to offer greater deference to rational priority setting.

Undue reliance on the prescribing physician's medical opinion is troublesome for three reasons. First, evidence suggests wealthier individuals from higher-income neighborhoods disproportionately file right to health claims, especially when private attorneys litigate, granting them unequal benefit to unique physician prescriptions.<sup>30-32</sup> Governments often decline

to add a product to the universal coverage benefits basket following a judicial order to provide it to an individual patient. The benefit is granted only to the person bringing the legal claim, unless the court expands its ruling to the entire patient class. This is particularly true in civil legal systems, where courts are not required to follow the precedent of prior decisions—each case stands on its own.

Second, the motivations of the prescribing physician in recommending uncovered products are not always clear. Even if patients are not primarily higher-income individuals with private representation, public representation of right to health cases may be just as worrisome. In many instances, civic associations or nongovernmental organizations (NGOs) file lawsuits on behalf of patients. The majority of patients do not know the name or location of the NGO or association filing on their behalf, NGOs often file claims on behalf of specific disease groups, and patient groups offering legal advice can be openly funded by pharmaceutical companies. This suggests that pharmaceutical companies may be playing an indirect role in sponsoring litigation to gain government support for their products.<sup>20,27,30,31</sup> A large percentage of cases can be filed by a small proportion of attorneys on behalf of prescriptions written by a modest proportion of physicians.<sup>31</sup> Again, this evidence invites the hypothesis of a relationship between NGOs, physicians, attorneys, and pharmaceutical companies.

Finally, physicians may make individualized decisions for their patients unsupported by the evidence.<sup>26</sup> In *Hernandez Edward vs. Fondo Nacional de Recursos*, the Uruguayan court granted a liver cancer patient access to Sorafenib, a drug placed on the country's Therapeutic Drug Roster for renal cancer and not general oncological treatment. The court determined it a “technicality” that the drug was covered for one type of cancer and not another, stating, “Prescriptions and therapies chosen by the physician cannot be dictated by politicians and administrative authorities.”<sup>33</sup> Drug rosters may sometimes be bereft of important and well-recognized uses for pharmaceuticals. However, where the government has made inclusion decisions based on clinical evidence, overturning those decisions can force the government to fund off-label prescribing or experimental treatments. A study by Norheim and Wilson reviewed 37 successful cases in Costa Rica in 2008 and found that approximately 70% of the decisions granted access to low-priority or experimental drugs (where priority was determined by the severity of the disease without the new drug and the effectiveness and cost-effectiveness of that drug).<sup>26</sup> The Brazilian health benefits basket includes a less expensive alternative for up to 80% of the drugs granted to patients by judicial order.<sup>32</sup>

Where the priority-setting efforts of a government are unscientific, unfairly developed, politically motivated, or have other flaws, judicial review of a government's decision to deny or fail to properly provide technology coverage is critical. In 2002, the Treatment Action Campaign challenged the South African government's creation of a public health program designed to mitigate mother-to-child HIV transmission. The program offered free Nevirapine at certain pilot sites to HIV-positive pregnant women to prevent transmission with no timeline for national expansion. The court held that the government was not taking reasonable steps to reduce mother-to-child transmission and ordered it to develop a comprehensive, countrywide program. It found that the government could reasonably utilize a pilot program to gather evidence on scalability and efficacy but could not wait until it had developed the best program to disseminate it nationwide.<sup>34</sup>

The South African case of *Minister of Health vs. Treatment Action Campaign* is highly regarded as a judicialization of the right to health success story. There are many other similarly successful cases. Some population-based rulings in Latin America, where civil law systems are prominent, have had similarly progressive effects. However, the differences between this case and those presented earlier are significant. First, the court's decision remedied an inequality of like individuals treated differently, strictly according to where they lived. Second, the court recognized the value in determining the efficacy of a treatment before offering it to the public. Third, the court identified and remedied a population-wide problem afflicting pregnant women with HIV, and its decision would go on to have an impact on that entire population.

This is not to say that proper judicialization of the right to health requires a population-based claim—in a number of instances, courts have granted individuals access to drugs internationally recognized to be clinically and cost-effective, such as antiretroviral therapy for HIV.<sup>35,36</sup> However, if decisions are made without any strategies for assessing the rationality of priority setting, the judicialization of the right to health may continue to put at risk the government's ability to utilize resources to maximize population-based health. The trend toward judicialization is growing; Thailand just overturned the government's decision to exclude glucosamine from its benefit package, marking its first ever case judicializing the right to health.<sup>37</sup> It is therefore becoming more important than ever to equip health systems with skills to engage in and defend rational priority setting. Courts must also be empowered with the tools, such as a thorough understanding of the need for, and process of, rational priority setting to determine the legitimacy of a government's inclusion or exclusion decision.

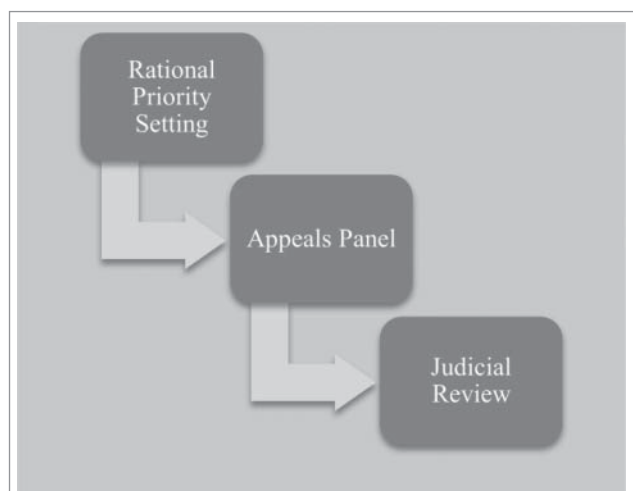
## SEEKING A NEW BALANCE FOR THE ROLE OF THE COURTS

Earlier, we argued that coverage decisions under a universal health coverage scheme should ensure fair allocation of resources in order to maximize population health. To ensure that such decisions are made, we should promote informed judicial decision-making and guarantee rational priority setting.

The strength and role of the courts in adjudicating the right to health will always vary across countries, especially considering the tendency of some judicial systems to be more deferential to government policy than others. Despite the variety across court systems, every health system could benefit from utilizing experts to represent the government's priority-setting decisions, with force equal to the patient's representation—thereby strengthening the health system's legal defense. Scientific experts could bring to bear methodologically sound studies rigorously evaluating the cost and effectiveness of medical products. Other health system experts could illuminate the social value judgments relied on to make coverage decisions. Evidence should support priority setting from a scientific standpoint (for example, by providing solid, clear evidence of the basis by which a product's coverage is denied) or a social standpoint—and not simply the administrative technicalities of priority setting. Experts could also strengthen the government's defense by arguing the collective impact that coverage would have if granted to everyone in need of the patient's desired product. Courts are better able to opine on the collective impact a decision would have on scarce resources.<sup>27</sup>

However, it would be insufficient to equip governments only with tools for better defense for three reasons. First, a weak defense is not always the problem. In certain instances, cases for access are argued before the health system has evaluated the value of that technology and the government has not yet collected the evidence required to support its decision for or against coverage.<sup>38</sup> Second, what if the government's priorities were irrational or misguided? The courts surely have a role in ensuring that the government has followed the procedures it has undertaken to follow and has abided by the criteria and principles by which it has said it would abide.

Finally, evidence suggests that courts sometimes lack trust in the priority-setting process that would make them comfortable relying on it. The Mexican Supreme Court recently postponed its decision to grant access to the expensive drug Eculizumab, requiring further review by the commission responsible for designing the benefit plan. In doing so, it recognized the need for external review of priority setting but



**FIGURE 1.** Three Stages of Accountability

also expressed concern that the commission to which it deferred might not meet transparency and other fair process standards.<sup>39,40</sup> Mexico's Supreme Court decision offers two important lessons: first, that courts may be willing to recognize their limitations on reviewing priority setting and, second, that courts desire the ability to defer to a fair, defensible priority-setting process. If we encourage countries to engage in rational priority setting to determine their benefits package, countries would then make the most evidence-based decisions about coverage that are defensible in court.

Countries differ greatly in access to resources for priority setting, capacity to conduct priority setting, and cultural and institutional interpretations of key priority-setting processes and values.<sup>23</sup> It would be infeasible to advocate a single, standardized system of rational priority setting. However, all countries could strive to engage in rational priority setting through an explicit, transparent, evidence-based approach, such as health technology assessment (HTA). Using results from clinical trials and epidemiological data on effectiveness, HTA identifies the health care products that work best, for whom they work best, how they compare to their alternatives, and how much demand they place on the health system's resources.<sup>41</sup> An assessment considers the social, economic, organizational, and ethical issues of a health intervention to inform policy decision-making.<sup>42</sup>

After an initial recommendation based on cost- and clinical-effectiveness and social considerations, HTA processes can include an appeals process for independent review of the prioritization decision by health system and health care experts. Many countries offer stakeholders the opportunity to

appeal (or request independent review) of the final recommendation or to seek judicial review.<sup>43</sup> The National Institute for Health and Care Excellence (NICE) offers a prime example. NICE functions as the National Health Service's HTA agency for England and Wales. As one of the leading HTA agencies internationally, NICE offers the opportunity to appeal its decision if it may have acted unfairly or exceeded its powers, or made a recommendation unreasonable in light of the evidence.<sup>44</sup> Even after the appeals panel makes a determination, the decision may still be appealed for judicial review based on grounds such as procedural unfairness, discrimination, or irrationality.<sup>45</sup> An opportunity for appeal (before judicial review) could be incorporated in HTA processes more widely.

Daniels' "accountability for reasonableness" principles are often invoked to guide a fair process of limit-setting decision-making.<sup>46</sup> Daniels argues that society may not reach a general consensus on what is necessarily fair prioritization, but four principles guide a fair *process* for prioritization. He suggests that it requires transparency, rationale for the relevance of the decision under resource constraints, a mechanism for challenging the decision, and regulation or enforcement of the process.<sup>46,47</sup>

Rational priority setting with the opportunity to appeal promotes accountability for reasonableness. The priority-setting process transparently considers the evidence and social values important to making a fair coverage decision, and it often invites stakeholder participation to make important decisions balancing the evidence with value judgments.<sup>48-50</sup> In doing so, countries can also strive to maximize population-based health while accommodating specific disease groups and marginalized populations according to society-specific values. An appeals process could offer the opportunity to challenge the validity of the decision, and judicial review the ability to ensure that the process of priority setting has been undertaken rationally. In theory, accountability for reasonableness increases transparency and the existence of intrinsic health system mechanisms for patients to challenge coverage decisions, which could deter them from turning to the court systems.

The way in which countries implement a three-step process of (1) rational priority setting, (2) appeal, and (3) judicial review (**Fig. 1**) will differ depending on resource constraints, political systems, and social values. The United Kingdom's experience suggests that courts embrace their role reviewing procedural fairness and rationality of NICE's decisions. Cases seeking access to a specific product may instead occur when NICE has not yet reviewed the intervention.<sup>51</sup> The experience of countries that have thus far engaged



heavily in the judicialization of the right to health could be quite different. However, as countries advance toward rational priority setting, they have an opportunity to ask critical questions about the impact that rational priority-setting processes have on the court's decision-making. Are courts more likely to uphold the government's exclusion decisions when they have been made using HTA or other rational priority-setting processes? Do courts rely on the clinical- and cost-effectiveness evidence demonstrating the collective impact of access to a product? Does the opportunity for appeal or judicial review decrease the number of right to health court claims?

Ultimately, encouraging countries to engage in rational priority setting through utilizing HTA addresses three major concerns with the judicialization of the right to health. First, the evidence resulting from the HTA process can present to courts hard cost- and clinical-effectiveness data and the social value judgments relied on to drive the government's priority-setting decision. Second, the structured process for priority-setting decision-making may give courts greater reliance on, and trust in, the government's decision to include or exclude a given product, responding to the hesitations expressed in the Mexican case considering Eculizumab. Finally, by considering clinical-effectiveness, cost-effectiveness, and social values, decision makers can account for the societal-level impact of, and need for, a technology. In doing so, they can be encouraged to consider equity-based principles to ensure a population-based right to health when engaging in rational priority setting.

However, the three stages of accountability will only succeed through cooperation between the courts, health policy makers, and government officials. In order for the courts to be comfortable reviewing the process of HTA rather than the decision itself, they must be certain that (1) the appeals process fairly reviews the coverage decision and (2) the initial HTA process rationally considers the social and scientific evidence. To do so, HTA processes should aim to utilize the evidence to make coverage decisions that treat like people similarly, just as the court aimed to remedy in *Treatment Action Campaign*. Governments can account for societal-level values and specific disease groups as they see fit but allocate resources equitably by ensuring that each member of a group is treated alike. If rational priority setting is evidence and equity based, courts can be empowered to rely more heavily on the government's coverage decision and instead assess the rationality of the process.

Implementing and cultivating rational priority setting will require the combined efforts of governments to adopt an appropriate process and courts to place greater weight in the

evidence—maximizing population health while being attentive to the vulnerable and marginalized. With such a balance, rational priority setting and the judicialization of the right to health can and should coexist. The courts should continue to play a fundamental role in overseeing procedural justice within rational priority setting and enforcing adequate delivery of the prioritized technologies.

## DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

No potential conflicts of interest were disclosed.

## REFERENCES

- [1] Klein R, Maybin J. Thinking about rationing. UK: The King's Fund; 2012. Available at [http://www.kingsfund.org.uk/sites/files/kf/field/publication\\_file/Thinking-about-rationing-the-kings-fund-may-2012.pdf](http://www.kingsfund.org.uk/sites/files/kf/field/publication_file/Thinking-about-rationing-the-kings-fund-may-2012.pdf) (accessed 27 September 2015)
- [2] Glassman A, Chalkidou K. Priority-setting in health: building institutions for smarter public spending. Washington, DC: Center for Global Development; 2012. Available at [http://www.cgdev.org/sites/default/files/1426240\\_file\\_priority\\_setting\\_global\\_health\\_FINAL\\_0.pdf](http://www.cgdev.org/sites/default/files/1426240_file_priority_setting_global_health_FINAL_0.pdf) (accessed 27 September 2015)
- [3] Li R, Hernandez-Villafuerte K, Towse A, Vlad I, Chalkidou K. Mapping priority-setting in health in 17 countries across Asia, Latin America and sub-Saharan Africa. *Health Sys Ref*, this issue.
- [4] Hogerzeil HV, Samson M, Casanovas JV, Rahmani-Ocara L. Is access to essential medicines as part of the fulfillment of the right to health enforceable through the courts? *Lancet* 2006; 368(9532): 305-311.
- [5] Biehl J, Amon JJ, Socal MP, Petryna A. Between the court and the clinic: lawsuits for medicines and the right to health in Brazil. *Health Hum Rights* 2012; 14(1): 36-52.
- [6] Cubillos L, Escobar M-L, Pavlovic S, Iunes R. Universal health coverage and litigation in Latin America. *J Health Organ Manag* 2012; 26(3): 390-406.
- [7] Yamin AE. The right to health under international law and its relevance to the United States. *Am J Public Health* 2005; 95(7): 1156-1161.
- [8] United Nations. The universal declaration of human rights. Available at <http://www.un.org/en/documents/udhr/> (accessed 5 September 2015)
- [9] Office of the High Commissioner for Human Rights. International covenant on economic, social, and cultural rights. Available at <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx> (accessed 1 September 2015)
- [10] UN Committee on Economic, Social and Cultural Rights. General comment no. 14: the right to the highest attainable standard of health (Art. 12 of the Covenant). August 2000. Available at <http://www.refworld.org/docid/4538838d0.html> (accessed 10 September 2015)

- [11] World Health Organization. Constitution of the World Health Organization. 2006. Available at [http://www.who.int/governance/eb/who\\_constitution\\_en.pdf](http://www.who.int/governance/eb/who_constitution_en.pdf) (accessed 1 September 2015)
- [12] Heymann J, Cassola A, Raub A, Mishra L. Constitutional rights to health, public health and medical care: the status of health protections in 191 countries. *Glob Public Health* 2013; 8(6): 639-653.
- [13] Brazil's constitution of 1988 with amendments through 2014, Rosenn KS, trans. n.d. Available at [https://www.constituteproject.org/constitution/Brazil\\_2014.pdf](https://www.constituteproject.org/constitution/Brazil_2014.pdf) (accessed 28 September 2015)
- [14] Haiti 1987 (rev. 2012), del Carmen Gress M, Ruchti JJ, trans. 2012. Available at [https://www.constituteproject.org/constitution/Haiti\\_2012?lang=en](https://www.constituteproject.org/constitution/Haiti_2012?lang=en) (accessed 20 September 2015)
- [15] Constitutional Court. Ms. Vera Salazar Navarro v. Caja Costarricense de Seguro Social, 01-0090007-CO Sept. 26, 2001 (Costa Rica).
- [16] Corte Suprema de Justicia de la Nación (National Supreme Court of Justice). Orlando, Susana Beatriz c/ Buenos Aires, Provincia de y otros s/ amparo. O.59.XXXVIII 2005 (Arg.).
- [17] Corte Suprema de Justicia de la Nación (National Supreme Court of Justice). Campodónico de Beviacqua, Ana Carina c/ Ministerio de Salud y Acción Social - Secretaría de Programas de Salud y Banco de Drogas Neoplásicas. C.823.XXXV Oct. 24, 2000 (Arg.).
- [18] Supreme Court Sitting as the High Court of Justice. Gila Louzon v. Government of Israel, HCJ 4013/05 Aug. 8, 2005 (Israel).
- [19] La Sala Segunda de Revisión de la Corte Constitucional [Second Review Chamber of the Colombian Constitutional Court]. Sentencia T-760 del 2008 [Judgement T-760 of 2008] July 31, 2008 (Col.).
- [20] Yamin AE, Gloppen S, eds. Litigating health rights. Cambridge: Harvard University Press; 2011.
- [21] Scheunemann LP, White DB. The ethics and reality of rationing in medicine. *Chest* 2011; 140(6): 1625-1632.
- [22] Krubiner CR, Faden RR. How to consider ethics and equity when designing a health benefits plan. In: What services should health systems provide? Health benefits in low- and middle-income countries, Giedion U, Glassman A, Smith PC, eds. Forthcoming.
- [23] Clarke S, Weale A. Social values in health priority setting: a conceptual framework. *J Health Organ Manag* 2012; 26(3): 293-316.
- [24] Ferraz OLM. The right to health in the courts of Brazil: worsening health inequities? *Health Hum Rights* 2009; 11(2): 33-45.
- [25] Civil Appeals Court, 2nd District. Marquez Velazquez Antonio Gerardo v. Ministry of Public Health, 39/10. March 10, 2010 (Uruguay).
- [26] Norheim OF, Wilson BM. Health rights litigation and access to medicines: priority classification of successful cases from Costa Rica's Constitutional Chamber of the Supreme Court. *Health Hum Rights J* 2014; 16(2): 47-61.
- [27] Wang DWL. Can litigation promote fairness in healthcare? The judicial review of rationing decisions in Brazil and England [dissertation]. London: London School of Economics; 2013.
- [28] Tribunal de Apelaciones en lo Civil de Cuarto Turno [Civil Appeals Court, 4th District]. Hernandez Gonzales, Eliu Aquiliano c/ Estado-Poder Ejecutivo-M.S.P. -Accion de Amparo [Hernandez Gonzalez, Eliu Aquiliano vs. Executive State Power of the Ministry of Public Health -writ of amparo 179/ 11 June 7, 2011 (Uruguay).
- [29] Ventura M, Simas L, Pepe VLE, Schramm FR. Judicialização da saúde, acesso á justiça e a efetividade do direito à saúde [Judicialization of the right to health, access to justice and the effectiveness of right to health]. *Revista de Saude Coletiva* 2010; 20(1): 77-100.
- [30] Afonso da Silva V, Terrazas FV. Claiming the right to health in Brazilian courts: the exclusion of the already excluded? *Law Soc Inq* 2011; 36(4): 825-853.
- [31] Lopes LC, Barberato-Filho S, Costa AC, Osorio-de-Castro CGS. Rational use of anticancer drugs and patient lawsuits in the state of São Paulo, Southeastern Brazil. *Rev Saúde Pública* 2010; 44(4): 1-9.
- [32] Machado MAA, Acurcio FA, Brandão CMR, Faleiros DR, Guerra AA Jr, Cherchiglia ML, Andrade EIG. Judicialization of access to medicines in Minas Gerais state, Southeastern Brazil. *Rev Saúde Pública* 2011; 45(3): 1-7.
- [33] Tribunal de Apelaciones en lo Civil de Segundo Turno [Second Chamber of the Civil Court of Appeals]. Hernandez Edward c/ Fondo Nacional de Recursos Accion de Amparo. [Hernandez Edward v. Fondo Nacional de Recursos (National Monetary Fund) Protection Action 393/2011 Dec. 21, 2011 (Uruguay).
- [34] Constitutional Court of South Africa. Minister of Health v. Treatment Action Campaign (No 2) [2002] ZACC 15 July 5, 2002 (South Africa).
- [35] Constitutional Court. Mr. X v. Instituto de Seguros Sociales (ISS) T-271 June 23, 1995 (Col.).
- [36] Supremo Tribunal Federal (Federal Supreme Court). State of Mato Grosso v. Marina de Almeida Andrade RE 400040/MT 2005 (Brazil).
- [37] Central Administrative Court. The case of administrative organization issuing unlawful regulation, AA (alias) versus Ministry of Finance 502/2558 February, 26 2015 (Thailand).
- [38] Torres JB, Stuwe L. Memorias. Segundo Encuentro Regional Sobre Derecho a La Salud y Sistemas de Salud [Minutes of the Second Latin American Symposium on the Right to Health and Health Systems]. December 2011. Available at [http://api.ning.com/files/R2K4gXWu4ReSrJzT9I\\*L2JGvpbmFa2Z\\*eOglGeEZv3onN3W5AjT6UoXh8F9evOHIGC87xVQHYaMzeMZJlrvG2dxHow6m/MemoriasdelSegundoEncuentroRegionalSobreDerechoaLaSaludySistemasdeSalud.pdf](http://api.ning.com/files/R2K4gXWu4ReSrJzT9I*L2JGvpbmFa2Z*eOglGeEZv3onN3W5AjT6UoXh8F9evOHIGC87xVQHYaMzeMZJlrvG2dxHow6m/MemoriasdelSegundoEncuentroRegionalSobreDerechoaLaSaludySistemasdeSalud.pdf) (accessed 2 November 2015)
- [39] Daniels N, Charvel S, Gelpi AH, Portney T, Urrutia J. Role of the courts in the progressive realization of the right to health: between the threat and the promise of judicialization in Mexico. *Health Systems & Reform* 2015; 1(3): 229-234.
- [40] Mexican Supreme Court. Amparo en Revision 350/2014, Segunda Sala de la Suprema Corte de Justicia de la Nacion [Motion for review in the Amparo trial, case 350/2014/] Sept. 17, 2014 (Mex.).
- [41] Chalkidou K, Marten R, Cutler D, Culyer T, Smith R, Teerawattananon Y, Cluzeau F, Li R, Sullivan R, Huang Y, et al.

- Health technology assessment in universal health coverage. *Lancet* 2013; 382(9910): e48-e49.
- [42] World Health Organization. Health technology assessment. n.d. Available at [http://www.who.int/medical\\_devices/assessment/en/](http://www.who.int/medical_devices/assessment/en/) (accessed 27 October 2015)
- [43] Wilsdon T, Fiz E, Haderi A. A comparative analysis of the role and impact of health technology assessment: 2013. 2014. Available at <http://www.efpia.eu/uploads/documents/cra-comparative-analysis.pdf> (accessed 10 September 2015)
- [44] National Institute for Health and Care Excellence. Technology appraisal and highly specialised technologies appeals. n.d. Available at <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/technology-appraisal-and-highly-specialised-technologies-appeals> (accessed 1 September 2015)
- [45] High Court of Justice Queen's Bench Division Administrative Court. *Eisai Limited and The National Institute for Health and Care Excellence and the Alzheimer's Society and Shire Pharmaceutical Limited* CO/85/2007 Aug. 10, 2007 (Eng.).
- [46] Daniels N. Accountability for reasonableness. *BMJ* 2000; 321 (7272): 1300-1301.
- [47] Rid A. Justice and procedure: how does "accountability for reasonableness" result in fair limit-setting decisions? *J Med Ethics* 2009; 35(1): 12-16.
- [48] Rawlins MD, Cuyler AJ. National Institute for Clinical Excellence and its value judgments. *BMJ* 2004; 329(7459): 224-227.
- [49] Tantivess S, Velasco PR, Yothasamut J, Mohara A, Limprayoonyong H, Teerawattananon Y. Efficiency or equity: value judgments in coverage decisions in Thailand. *J Health Organ Manag* 2012; 26(3): 331-342.
- [50] National Institute for Health and Care Excellence. Methods for the development of NICE public health guidance (3rd ed.). 2012. Available at <https://www.nice.org.uk/article/pmg4/chapter/3-determining-the-evidence-for-review-and-consideration> (accessed 24 October 2015)
- [51] Court of Appeal, Civil Division. *R (on the application of Rogers) v. Swindon NHS Primary Care Trust and Another* [2006] EWCA Civ 392 April 12, 2006 (Eng.).