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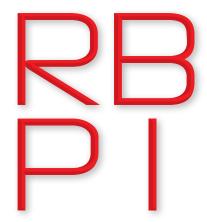
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Global Health and Economic Law: Private sector regulation on the global agenda

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Abstract

Covid-19 and discussions in Brazil about the distribution of ICU beds stressed the enormous difficulty of guaranteeing health as a right in a public-private system, something that was already known. Enforcing health as a right depends, more than ever, on prioritizing both universality and equity. This article argues that this requires a new framework in both the legal field and the global health field, that of Global Health and Economic Law, which in this article is examined with a focus on the health care industry.

Keywords: Public-private; Health care system; Global Health; Economic Law; Health Care Industry.

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Introduction

The new coronavirus pandemic has had an overwhelming impact on our society. In addition to causing millions of deaths and global impoverishment, it has clearly shown how contagious diseases can affect people unequally: socially and economically vulnerable populations have succumbed at a much faster pace than other people, even though the virus is unable to discriminate between human beings.

Several weaknesses have been exposed, including: the lack of adequate social security policies, lockdown measures disconnected from food security policies, abuse of censorship, criminalization and police surveillance, little to no securement of the most vulnerable people—e.g., the elderly, migrants, children, women, and minority groups stigmatized by the supposed origin of the virus (see Davis 2020). Another weakness has been the fact that frontline health care workers have faced various assaults and unsafe work conditions (Amnesty International 2020). In Brazil, the dramatic absence of a policy to protect the indigenous population is also noteworthy.

Unequal access to ICU (intensive care unit) beds in the Brazilian public-private system have partially accounted for the unequal mortality rates amongst the Brazilian people. In fact, Baqui et al. (2020, 6) showed that a higher mortality rate among Pardo (brown) and Black Brazilians compared to that of White Brazilians has been most likely related to the greater difficulty that the former has to access ICUs in the public-private system.

In the 2000s, the impact of recognizing health as a right was largely linked to the effects of 1) the emerging Unified Health System (known as SUS – acronym in Portuguese for Sistema Único de Saúde), 2) the new health insurance market regulation, and 3) litigation of the right to health within the public-private system. Nonetheless, it seems that in the post-Covid-19 era the impact of recognizing health as a right will be especially assessed by its ability to drive the public-private system towards universality and equity.

Even before Covid-19, welfare states that had managed to forge more egalitarian systems were already fearful of the risks posed by a growing private sector. Besides, it is already known that public health surveillance and emergency measures are insufficient to secure global health. It has become apparent that strengthening national health care systems, especially organized around equity, is fundamental to secure global health.

Therefore, it seems to be high time that research and debates explore the intersection of Global Health, the Right to Health, and Economic Law. To demonstrate this, the present article is divided into four sections as follows.

Section 1 is based on the book The Right to Health at the Public/Private Divide – A Global Comparative Study (Flood & Gross 2014), which relates the right to health to challenges for building egalitarian systems in the current public-private context. This book comprises 16 chapters on the health care systems of 16 different countries, which were classified according to what extent they acknowledge health as a right and to what extent they provide public funds to their health care systems. Its introduction explains that "this framing puts heavy emphasis on the extent to which different mixes of public and private financing interact with health care rights, yielding differing levels of access and equity in health care." (Flood & Gross 2014,6). This leads to different analyses as to how litigations or levels of access to justice interfere with resources allocation, protection of vulnerable populations, etc. Even though other articles or books have addressed the topic, The Right to Health at the Public/Private Divide - A Global Comparative Study on its own leads to two conclusions: 1) at least at this moment, research on "health rights litigation" seems to be unproductive in showing the usefulness of acknowledging the right to health as a way to effectively secure the health of the most vulnerable population in countries with dual public-private systems, and 2) this topic has a global nature and impact. These conclusions beg the question: what legal instruments can increase the access of the most vulnerable populations to national public-private health care systems, as they are the most common type of system throughout the globe?

Section 2 provides the concept of Global Health *and* Economic Law and points to the need to introduce it as a research field and a debate topic within health law and global health,

considering the increasing public-health dichotomy in the national public-private health care systems throughout the globe and the relevance of the human rights theoretical framework for the topic. The notion of right to health, from the perspective of Global Health and Economic Law, can be directed to different sectors of the economy or groups of industries and services, depending on the goal established by each country. For instance, Economic law could be focused on "new health technologies," expanding access to medication while also guiding and systematizing a set of national rules on the incentives for national technological innovation, on the criteria for including new technologies into the national systems, and on the parameters for the operation of pharmaceutical industries. Economic law could also be focused on "health and food," systematizing a set of rules related to agriculture, food industry, and pesticide industry. All these sets would obviously interact, as they all should and must articulate through and around health and what we call Global Health and Economic Law.

Nevertheless, it would be impossible to address all these sets in one single article aimed at showing the usefulness of Global Health *and* Economic Law for future research on the right to health. Therefore, this article focuses on the economic right that specifically affects the health care industry and its direct providers. To this end, it draws on data and articles that have addressed the regulation of components of the "health care industry," even though the recognition of internal borders within health systems are tenuous and require constant revisions in the field of health.

Section 3 discusses how Covid-19 has led to a major increase in the number of ICU beds in Brazil. It shows that 1) most of these beds do not belong to the Unified Health System, but rather to the private sector, and 2) most of them are temporary. On the one hand, these data reinforce the need to understand the use of such beds, the policies for creating and terminating beds, and the development of proper regulation in this sector. On the other hand, they show striking inequalities in fundamental aspects of access to health and significant ignorance of equity-oriented norms and policies for the private health sector. This ignorance – which was identifiable long before Covid-19 – has only become more apparent.

Section 4 proposes a new research agenda related to the study of the public-private sector in the domain of global health. It shows how "National Health Care Systems," the "Right to Health" and "Global Health" are related to each other and points out the questions and challenges surrounding the regulation of three components of the private sector that integrate the national health care systems (medication purchase, voluntary health insurance, and health workforce). Ultimately it points to the need for a new articulated research agenda towards equity and universality.

The right to health in the face of the public/private divide: A global problem

Health care systems around the world have faced the same challenges, albeit in different forms and to different extents: To what extent should funding be public? How to regulate the private

sector? Recent research has sought to answer these questions by exploring how advances in equity relate to both public-private financing and enforcement of health as a right.

The starting point of the book *The Right to Health at the Public/Private Divide – A Global Comparative Study* is an intriguing inquiry:

Does the recognition of a right to health care help sustains public values (like equality) in systems that are undergoing privatization? Or, to the contrary, does a focus on rights-based norms foster individualism and exacerbate inequalities brought about privatization? (Flood & Gross 2014,1)

In said book, authors from different countries particularly explore 5 major issues:

- 1) the extent to which health rights litigation may serve to undermine a fair allocation of resources within a health care system,
- 2) the fact that the progressivity of human rights litigation cannot be readily disentangled from access to justice issues,
- 3) how law and judicial decisions operate within a larger sociopolitical context,
- 4) the impact of litigation of constitutional rights versus the impact of rights contained in domestic legislation,
- 5) if courts are the best venue to improve equity or fairness. (Flood & Gross 2014,13/16)

Rich in both data and analysis, the articles do not provide easy solutions, as one would expect, but the result is invaluable. They show that universal, national tax-financed systems (e.g., in Canada, the United Kingdom, Sweden, and New Zealand) built within social welfare states generally have remained robust and committed to their redistributive purpose (with the healthy and the rich financing the sick and the poor), even though they do not recognize the right to health as a legitimizing factor for individual lawsuits.

In contrast, the group of public-private systems (e.g., China, Brazil, Colombia, South Africa, the United States, Nigeria, Venezuela, and India) has provided a lower percentage of public health financing, with a significant share of contribution from the private sector. This has occurred even though most of such systems have health recognized as a right in their post-1989 re-democratization constitutions, precisely to ensure a more egalitarian welfare state.

Flood and Gross (2014) provide no clear conclusion about the positive or negative effects of health rights litigation in Brazil. The authors point to both improved policies and dubious effects on the advances in equitable allocation of public resources. They draw the following conclusion about the group of countries that includes Brazil:

[...] But in assessing the impact of litigation in these systems, it is important that we avoid, as it were, mistaking the trees for the forest. From a social justice perspective,

court victories expanding coverage for individuals or groups within the public system are overshadowed by this larger cleavage between poorly financed systems and well-financed private systems. To date, there is scant evidence that health rights advance equity across the public and private systems that operate in parallel in these countries. (Flood & Gross 2014, 471)

As said before, one of the greatest merits of the book is pointing to the need to establish new study fronts focused on the right to health, while recognizing the limitations and exhaustion, at least at this moment, of litigation as an instrument for enforcing rights in public-private health care systems. As well noted, the enforcement of the right to health depends to a large extent on building good health care systems, i.e., systems that prioritize the securement of equity, which have somehow proved to be independent of legal securement of health. In other words, it is clear that health as a right experienced by all stems more from a state of cultural and civilizing progress in the country than from introducing a legal norm and eventually facing its judicial controversies.

As a conclusion, litigation is a relevant part, but it does not contain all the potential for recognizing the right to health. Furthermore, recognizing that courts do not and should not be responsible for establishing an "egalitarian" health care system does not entail that they do not have a relevant role to play. We agree with Flood and Gross (2014, 469) when they say,

We argue that courts should be more willing than they presently are to scrutinize policy measures that are retrogressive, and push systems toward a commitment to universal, public health care that secures access on the part of those most in need. We argue for this not because courts can replace policy decisions, but rather because we see a role for courts in holding governments to a standard of rationality and reasonability and ensuring that governmental decision making adheres to human rights standards [...].

On the other hand, the Covid-19 pandemic has accelerated the urgency to discuss global health from its ethical perspective. Data from different regions of the globe point out that Covid-19-related risks of death and worsening health conditions have affected the population unequally, striking the most vulnerable people (e.g., in regard to race, gender, and socioeconomic condition) more abruptly.

In addition, the new coronavirus pandemic has also made evident that health as a human right is key for the regulation of more egalitarian health care systems, especially in countries, such as Brazil, where this right has emerged as part of a historically recent (re)democratization process. In fact, the pandemic has reinforced an existing demand for opening up new legal perspectives for research relating the right to health care and global health within public-private health care systems.

Defining Global Health and Economic Law with a focus on Health Care Systems

Gostin and Taylor (2008, 234) pointed to the need to build a coherent global health law framework and provided a definition of its content and objectives:

Global health law is a field that encompasses the legal norms, processes, and institutions needed to create the conditions for people throughout the world to attain the highest possible level of physical and mental health. The field seeks to facilitate health-promoting behaviour among the key actors that significantly influence the public's health, including international organizations, governments, businesses, foundations, the media, and civil society. The mechanisms of global health law should stimulate investment in research and development, mobilize resources, set priorities, coordinate activities, monitor progress, create incentives, and enforce standards. Study and practice of the field should be guided by the overarching value of social justice, which requires equitable distribution of health services, particularly to benefit the world's poorest populations. (Gostin & Taylor 2008, 234)

Since then, proposals for new research focuses have emerged to understand the private sector and its regulation from the Global Health perspective. Specifically in the field of health care systems, the Global Initiative for Economic, Social and Cultural Rights (2019) argues in its report for the impact assessment of private health services based on the human rights framework. The report details the government's obligations in regard to the private sector and presents a large questionnaire as a parameter for this assessment. For instance, the report provides a set of questions for assessing the availability of health goods, establishments, and services:

How does private actor involvement affect the availability of:

- health care to promote and secure physical and mental health, including primary health care?
- good quality operational hospitals and clinics?
- trained health professionals receiving domestically competitive salaries? In particular, are health professionals for the public sector lost to the private sector?
- essential medicines as defined by the World Health Organisation? In particular, are medicines produced based on need rather than profitability?
- programmes for prevention, treatment and control of epidemic and endemic diseases?
- primary, secondary and tertiary care facilities?

National health care systems-focused economic law aims to go beyond periodic assessments and progressivity. It is about organizing, elaborating, and comparing the groups of norms that regulate the set of industries and private services related to the health care system with the specific

objective of designing and seeking the most effective models to secure the health of the most vulnerable population in the national public-private systems.

The legal debate, especially on Global Health Law, should include research related to Economic Law that contributes to expanding our legal-regulatory knowledge (rules, institutional designs, and policies) of both the health markets and the public-private divide in health, with a view to identifying and understanding the best instruments for promoting equity and enforcement of health as a right in different countries. In other words, it is a matter of systematizing the design of institutional rules and norms for the private health sector.

Besides, as mentioned above, combining the analysis of different public-private sectors under the banner of Global Health *and* Economic Law can contribute to developing distributive ethic-based normative frameworks for the private sector and eventually improving health law. Nevertheless, it is within Global Health, a transdisciplinary branch aimed at sustainable solutions based on the securement of human rights, that innovative solutions, including legal ones, can emerge to face complex health problems:

Within the normative framework of human rights, global health is a system-based, ecological and transdisciplinary approach to research, education, and practice which seeks to provide innovative, integrated, and sustainable solutions to address complex health problems across national boundaries and improve health for all. (Wernli et al. 2016, 3)

Ventura et al. (2020, 3) also highlight the importance of the Brazilian perspectives to the international literature on Global Health, especially the studies on the circulation, diffusion, and global transfer of policies:

[...] From the point of view of international academic cooperation, the initiatives in South America and the Global South should be prioritized. Promising methodological paths can be explored, such as studies on the circulation, dissemination, and global transfer of public policies. Methodological training to conduct case studies and the improvement of comparative case study methodologies are also highly relevant. (Ventura et al. 2020, 3)

Certainly "health economics," "policy," and "law" have already been introduced to the global academic agenda. However, the proposal is to centralize and streamline a specific debate within the global agenda, with a view to promoting research on private health sector regulation and eventually producing distributive effects and gains in equity and universality.

None of this means downplaying criticisms of and questions about the under-financing of public health care systems and their privatization or public funding. Strong public health care systems continue to be a fundamental condition for global health sustainability, and it is necessary to keep a close watch on governmental actions and international policies to be adopted

by organizations such as the International Monetary Fund (IMF) and the World Bank in the post-Covid-19 era (Bretton Woods Project 2020).

It seems urgent, however, to pave a parallel avenue. Economic Law, within the scope of Global Health Law, allows us to expand the legal-regulatory knowledge of markets and health-oriented public-private partnerships, define goals and specific objectives, and elaborate policies and institutional designs based on successful experiences of human rights enforcement. This calls for adding a new focus to the agenda of Global Health and Right to Health.

Comparato (1978, 457–458)¹ contends that in the post-World-War European economic crisis, Law started "to transform and systematize the economy-oriented norms²," which might first have been aimed at inflation control and country reconstruction, but later targeted "the arms race, the concentration of economic power in industrialized countries, and the 'Third World' development policy"³,⁴. Economic Law has emerged as "the normative discipline of government action upon the

¹ Fabio Konder Comparato is Full Professor and Emeritus at the School of Law, Universidade de São Paulo (USP). He holds a law degree from USP (1959) and a doctorate in Law from Université Paris 1 (Panthéon-Sorbonne) (1963). He is a specialist in Philosophy of Law, Human Rights, and Political Law. He is the author of numerous reference works in Brazil on Economic Law and Human Rights. In the words of Alessandro Octaviani (2008, 44/45): "I consider it possible to present Comparato's contribution to the reading of a Brazilian legal tradition concerned with overcoming underdevelopment, combining his theoretical production in private law, his suggestions for constitutional reorganization, and his postulation of 'indispensable economic law', drawing on the need to build the 'ability to govern'. His reflection on private law is largely concerned with placing it within the reach of public control, which transcends individualism and legal formalism characteristic of nineteenth-century liberalism: his proposals for constitutional and institutional reorganization are aimed at overcoming underdevelopment, postulating strong popular participation; and economic law seems to me to emerge in this reflection as an instrument for organizing the ability to govern in order to overcome underdevelopment.". Author's translation to "Avalio possível apresentar a contribuição de Comparato para a leitura de uma tradição jurídica brasileira preocupada com a superação do subdesenvolvimento costurando sua produção teórica em direito privado, suas sugestões de reorganização constitucional e a postulação de um "indispensável direito econômico", a partir da necessidade apontada pelo autor de construir a "capacidade de governar". Sua reflexão sobre os institutos de direito privado é em larga medida preocupada em coloca-los sob o alcance de um controle público, que transcenda o individualismo e o formalismo jurídico característicos do liberalismo do século XIX: suas propostas de reorganização constitucional e institucional são vertidas à superação do subdesenvolvimento, postulando uma forte participação popular; e o direito econômico me parece surge nessa reflexão como instrumento para a organização da capacidade de governar para superar o subdesenvolvimento.

² Author's translation to: "a transformar e sistematizar as normas de conteúdo econômico" (Comparato 1978, 458).

³ Author's translation to: "corrida armamentista, ao movimento de concentração do poder econômico nos países industrializados e a política de desenvolvimento do 'Terceiro Mundo" (Comparato 1978, 458).

⁴ Comparato (1978, 457–458) explains the emergence of Economic Law as follows:

Following the 1929 deflation and overproduction crisis, the World War II shook the European economies with the opposite problems of poverty and inflation. To cope with the war tasks and the reconstruction tasks in the aftermath as well as to eliminate surplus demand and abundance of currency in the market, the government used new processes to capture people's savings, ranging from compulsory lending to the systematic issue of government bonds competing with the open market. In turn, the distribution of the national product is rationalized through compulsory contingency, storage, and production, sale or foreign trade licensing measures. Hence, Law lends itself to economic content, while the economy becomes more administrative or regulated, i.e., legal.

In reproducing the post-World-War-I phenomenon to account for new goals, the contemporary law have tended to transform and systematize the economic-laden normative provisions that stemmed from the needs of war, instead of eliminating them. Several facts may explain this undeniable trend: the arms race, the movement to concentrate economic power in industrialized countries, and the 'Third World' development policy. (Comparato 1978, 457–458)

[[]Sucedendo à crise de deflação e de superprodução de 1929, o advento da segunda guerra mundial veio abalar as economias europeias com os problemas opostos de penúria e de inflação. Face às tarefas da guerra e da reconstrução que se lhe sucede e a fim de eliminar a procura excedentária e a abundância de signos monetários no mercado, o Estado lança mão de novos processos de captação da poupança popular, do empréstimo compulsório à emissão sistemática de títulos da dívida pública em concorrência com os privados (open market). Por outro lado, a repartição do produto nacional é racionalizada através de medidas compulsórias de contingenciamento, de estocagem, de licenciamento da produção, da venda ou do comércio exterior. O Direito deixa-se assim penetrar de conteúdo econômico, ao mesmo tempo que a economia se torna sempre mais administrativa ou regulamentada, isto é, jurídica.

Ora reproduzindo o fenômeno verificado após a primeira guerra mundial, o direito contemporâneo, longe de eliminar as disposições normativas de

economic system structures, whether centralized or decentralized"⁵ (Comparato 1978, 457-458). It is "one of the branches of applied law whose unity or, rather, autonomy is granted to us for its very purpose: normatively translating the instruments of the government's economic policy"⁶ (Comparato 1978, 471). Global Health *and* Economic Health can unite, organize, and compare state norms and national and international policies related to the private health care structures aiming to understand how they operate and how effective they are to produce distributive effects and gains in equity and universality.

It is worth noting that even before the Covid-19 pandemic, welfare states that had managed to forge more egalitarian systems were already fearful of the risks posed by a growing private sector. Besides, it is already known that public health surveillance and emergency measures alone fail to secure global health. It has become clear that strengthening national health care systems, especially organized around equity, is fundamental to secure health.

In most countries the recognition of health as a human right is still the ethical and strategic foundation to secure the health of the population in general and the most vulnerable people in particular, whether it is expressly recognized in national legal documents or not. It is precisely on the basis of the right to health that it is possible to guide a democratic regulation in a broad sense, one which includes standardization as produced by the Legislative and Executive Powers, standardization as produced by regulatory agencies, and design of health economic law policies.

Even though Economic Law in Brazil is predominantly concerned with broader themes such as overcoming underdevelopment and antitrust, there is, in theory, no obstacle to focusing on conducting the economic game within health care, i.e., on directing its actors, in the case of the Health Care Industry, to contribute to equity and universal access to health services. On the contrary, in times of neoliberalism, Economic Law needs to adopt other perspectives as an important part of the discipline as a whole, considering its broader issues while stipulating specific objectives in different sectors.

In the international field, both the World Trade Organization (WTO) and the European Union (EU) regulate health care services, whether as an international organization or provided by health care professionals in transit, with a view to widening an international commerce trade and movement of people. This perspective may or may not converge with the principles of equity and universality that we believe Economic Law should adopt, which depends on each sector and each national health care system. However, these are two different perspectives. Therefore, the manuscript now highlights that Economic Law is not built on free trade, which is a cornerstone to traditional property and freedom rights. In championing universal access to

conteúdo econômico originadas das necessidades de guerra, tende ao contrário a transformá-las e a sistematizá-las, em função de novos objetivos. Vários fatos explicam essa tendência incontrastável: a corrida armamentista, o movimento de concentração do poder econômico nos países industrializados e a política de desenvolvimento no 'Terceiro Mundo'. (Comparato 1978, 457/458)]

⁵ Author's translation to: "a disciplina normativa da ação estatal sobre as estruturas do sistema econômico, seja este centralizado ou descentralizado" (Comparato 1978, 457–458).

⁶ Author's translation to: "um dos ramos de direito aplicado cuja unidade ou, se preferir, sua autonomia nos é dada pela sua finalidade: traduzir normativamente os instrumentos da política econômica do Estado" (Comparato 1978, 471).

health care services, Economic Law may, for instance, adopt quite restrictive regulations, like the one adopted by the Medical Services Commission of British Columbia (Canada) described in Section 4.

Covid-19 and the public-private health sector in Brazil: New evidence of a well-known challenge

Baqui et al. (2020, 5) related Covid-19 hospital mortality to ethnic group in Brazil and clearly showed how difficult it is for Black and Pardo (Brown) Brazilians to access ICU beds in the public-private system:

ICU access might be a factor for regional and ethnic variations in mortality, with white Brazilians more likely to be admitted to ICU once hospitalised. Although White Brazilians were more likely to survive overall, we observed similar proportions between White and Pardo ethnicities when comparing total hospitalisations with deaths after ICU admission. The distribution of comorbidities, symptoms, and age did not show strong ethnic variations, especially between Pardo and White Brazilians (figure 3). The greater proportion of deaths without admission to ICU for Pardo Brazilians is noteworthy and likely to reflect higher levels of access to private health care for White Brazilians compared with that for Pardo Brazilians, because ICU admission policies are known to differ between public and private hospital settings. Private health care serves only 25% of the Brazilian population and total spending is similar to that of public health care, implying that, on average, a patient in a private hospital costs three times more than one in a public hospital. The proportions of the different ethnicities admitted to ICU with COVID-19 were similar to those in the full 2019 SIVEP-Gripe dataset, suggesting that this is not a specific feature of COVID-19 treatment [...].

The legal discussions on the subject demonstrate the open conflicts in the Brazilian society surrounding the public-private access to the health care system. At the beginning of the pandemic, two cases⁷ were brought to the Supreme Federal Court (STF – Portuguese acronym for *Supremo Tribunal Federal*) seeking to oppose measures: one intended to ensure the prompt unification of public and private ICU beds in the Brazilian health care system, and the other sought to limit the municipal and state governments' power to require private goods while demanding a central coordination by the federal government.

Cotrim and Cabral (2020) pointed out the various inequalities in the distribution of ICU beds in Brazil, providing data about the beds that existed before (December/2019) and after the pandemic (April/2020). In December 2019, Brazil had 46,045 ICU beds: 23,049 were

⁷ The cases are: ADPF 671/2020 (http://portal.stf.jus.br/processos/detalhe.asp?incidente=5884983) and ADI 6362/2020 (http://portal.stf.jus.br/processos/detalhe.asp?incidente=5886574).

public, and 22,996 were private. In April 2020, this number increased to 60,265 ICU beds: 26,153 public, and 34,112 privates. In other words, the number of ICU beds increased by 23.59% within four months, which is quite an impressive figure (Cotrim & Cabral 2020, 4). However, only 3,104 out of the 14,220 new beds were public (21.82%), while the remainder (11,116 new beds) was private. A significant part of these beds is temporary as they have been allocated in field hospitals.

In the North Region, for example, more than 90% of the population does not have health insurance. However, public beds in this region increased from 1,501 to 1,793 while private beds increased from 854 to 1,335 (Cotrim & Cabral 2020, 4). At first such data do not point to any strengthening of the Unified Health System as a consequence of the pandemic. On the contrary, they strongly indicate how important it is to understand the use of such beds (whether exclusive to one sector or to mixed public-private use), the distribution of beds across the Brazilian regions, the existence of unified waiting line policies in each region, the functioning of possible public-private partnerships, etc.

In other words, the pandemic in general and the discussions around the ICU waiting lines and the implementation of new ICU beds in particular have unveiled the difficulty of enforcing health as a right in the Brazilian public-private system. Theoretically, in a country where health is recognized as a fundamental human right, responses to situations of collective need of this magnitude should be quick and effective through distributive policies aimed at allocating unquestionably fundamental resources, such as ICU beds, based on health needs rather than on one's ability to pay.

Several reasons can be pointed out as a cause for this difficulty, including: the federalism of a country of continental dimension, political polarization, public under-financing within a neo-liberalism framework recently accentuated both at the national and the global levels. Among such reasons is also the absence of instruments and disseminated knowledge of the best regulatory practices in the private sector when it comes to health care systems that seek to secure health as a right.

Undoubtedly, conflicts over the distribution of ICU beds have existed in several countries and have been regulated in different ways, with better and worse results. For this reason, expanding and centralizing studies on regulatory frameworks (standards, institutional designs, and policies) in the private health care sector should be the subject of a global health care system-strengthening agenda. This is a challenging issue that deserves special attention from both Law and Global Health perspectives.

However, it has become clear that even a country with the economic and political dimension of Brazil is a vulnerable party in vaccine purchase agreements, such as those currently negotiated with large multinational companies. This begs such questions as: How to regulate the commercial interests of these companies in the face of the essential public good they produce? And once produced, how to secure access to and at the same time agree upon the global distribution of these goods? What kind of priority should be agreed upon?

Both the distribution of private ICU beds and the purchasing of technologies in a health emergency situation have clearly unveiled a reality that has been around long before the pandemic: the lack of legal-regulatory knowledge (rules, institutional designs, and policies) of the private health care sector in Brazil and in the globe. In fact, the Covid-19 crisis has served to reinforce the need and urgency to carry out research that identifies and compares legal and regulatory frameworks in different contexts, cultures and regions, while also analyzing such frameworks in the light of the political and economic interests of global health.

The maturation of Global Health Law requires the recognition of an Economic Law (see Bodra 2020) to prioritize research on these frameworks, with a view to identifying and pointing out the best instruments for promoting equity and securing health as a right through a normative organization of health-related economic activities, especially those in the public-private health sector. In addition to identifying these instruments, accumulating the analysis of different public-private health sectors (ranging, for example, from the distribution of private beds to the criteria for the purchase of essential technologies) under the banner of Global Health *and* Economic Law (here with a focus on health care systems) can encourage the development of distributive ethic-based normative frameworks that are appropriate to the private sector, which is essential for improving the regulation of health law.

Health Care Systems, Right to Health, and Global Health

In Lobato and Giovanella's (2012, 109) words, health care systems are the result of a set of political, economic and institutional relationships responsible for the processes related to the health of a population. While all systems have a given form of organization (e.g., service network, financing), health care systems cannot be separated from the society in which they find themselves. As the health care systems are part of a social dynamic, they are always related to the other social systems of a certain time and place (Lobato & Giovanella's 2012, 109).

As all contemporary societies have a national and a global dimension, health care systems and their dichotomies also relate to these two dimensions. Therefore, one of the greatest challenges for structuring health care systems is precisely to regulate the public/private divide based on the understanding of each society's characteristics in their national and global dimensions. In addition, designing an effective "regulation" of these sectors necessarily involves the possibility of comparing the different models used around the world.

As such, the right to health provides a unique and fundamental reference (set of principles and values) to guide the development of such regulatory framework. On the one hand, it directs the system towards positive health indicators and the securement of rights; on the other hand, it allows the design of unique models based on the needs and characteristics of each region and each locality.⁸

⁸ It is important to notice that Health Democracy is a fundamental principle of Health Law. For an understanding of the topic in Brazil, please refer to Aith (2017).

In turn, global health is a field of research and reflection that has emerged from the growing interdependence across nations, with an immense potential to strengthen national health care systems. In fact, it was well established before the Covid-19 pandemic, which has only contributed to making it even more relevant. Recognizing strategic themes within global health not only brings visibility and amplifies research and debates aimed at strengthening health care systems, but also garners attention to local challenges that can only be faced globally.

Research is of the essence to explore instruments and models adopted by different countries considering their historical, economic and social contexts (see, for instance, Flood & Gross 2014). A case in point is Joanna Manning's description of the New Zealand pharmaceutical management agency's successful operation:

Access to publicly funded pharmaceuticals is regulated by means of a pharmaceutical management agency, Pharmac. Its objective is to ensure that public money spent on pharmaceuticals is invested efficiently and achieves best value for the money. A key role is to manage the Pharmaceutical Schedule, which is a list of subsidized prescription drugs and related products. Pharma makes the final decision on subsidy levels and prescribing guidelines and conditions by balancing evidence of effectiveness with cost, within a fixed annual budget. It receives independent expert medical advice to inform its decisions from the Pharmacology and Therapeutics Advisory Committee (PTAC) and other specialist subcommittees. It uses cost-utility analyses to assess the important, often decisive cost-effectiveness criterion, which is one of nine criteria, for its prioritization decisions. Compared to many overseas countries, which have experienced significant growth in pharmaceutical expenditure, New Zealand has been highly successful in curbing the relentless growth in the rate of pharmaceutical spending. Despite this, an expert panel concluded in 2010 that there does not appear to be evidence that health outcomes in New Zealand are worse overall than for other comparable counties, largely because it pays lower prices for medicines than do most comparable countries, and so achieves relatively good value for the money. (Flood & Gross 2014, 21-22)

This description raises numerous questions about the criteria used to analyze and select technologies, the arguments used to define priorities, and the institutional design of an independent panel. It also arouses interest in the designs adopted by other countries. It lays bare the importance of a research agenda targeting successful policies, norms, and institutional designs that contribute to the equity of health care systems and to the enforcement of health as a right based on each country's context.

Relevant studies have already been carried out in this regard. It is already known, for instance, that one of the major challenges for developing health workforce is the "regulation of health care professions as a policy involving concerted efforts" (Padilla 2020, 6). In 2020 the Pan American

⁹ Author's translation to: "regulamentação das profissões de saúde como um assunto de política pública, que envolve esforço concentrado" (Padilla 2020, 6).

Health Organization (PAHO) and the Center for Health Law Studies and Research (Cepedisa – acronym for Centro de Estudos e Pesquisa de Direito Sanitário) published a relevant study on the Regulation of Health Professions in Brazil from a comparative perspective:

The PAHO/WHO have proposed three strategic courses of action, namely: 1) strengthening the governance of health care workforce, 2) develop conditions and capacities to expand access to health care and health coverage with equity and quality, and 3) develop responses to the call for universal health care alongside the educational sector. The first action is precisely the focus of this publication and requires from all countries in the region – and certainly in the world – a consistent, positive, concerted dialogue aimed at defining health-relevant social agreements. 10 (Padilla 2020, 6–7)

Said study presents the regulation of health care professions considering the different historical and social contexts of several countries, including Brazil, Argentina, Paraguay, Uruguay, Canada, India, and South Africa. It also contains a specific chapter on the European Community and a special analysis of Canada. A case in point is the *Waldman versus The Medical Services Commission of British Columbia*¹¹ case, which evinced the regional price control policy of health care services as a mechanism for distributing health professionals across Canada:

The Waldman versus The Medical Services Commission of British Columbia, or simply Waldman, case was a legal dispute that reached the Supreme Court of British Columbia and involved a health care workforce-related policy. Despite its provincial level, it has gained notoriety in the field of Health Law. The Medical Services Commission of British Columbia had the competence to define the rate of services to which medical professionals should respond in their duties. Three physicians challenged in court the methodology that the commission used to calculate each physician's fee, which was based on the place of practice. (Aith 2020, 333)

¹⁰ Author's translation to: "Das três linhas de ação estratégicas propostas pela OPAS/OMS – fortalecer e consolidar a governança e a reitoria de recursos humanos em saúde; desenvolver condições e capacidades para expandir o acesso e a cobertura da saúde com equidade e qualidade; e acordar com o setor educacional respostas às necessidades dos sistemas de saúde em transformação para a saúde universal – o primeiro refere-se precisamente ao assunto que esta publicação oferece e requer de todos os países da região – e, certamente, do mundo – um exercício integrado e consistente de diálogo positivo para a construção de acordos sociais relevantes para a saúde." (Padilla 2020, 6–7)

¹¹ The Medical Services Commission of British Columbia (Canada) regulates the provision of medical services based on the population's need and the government's ability to pay. Among other measures, the Commission issues rules defining each physician's fee in each region to encourage an equitable distribution of professionals across the regions. In the Waldman case, physicians Deborah Judith Waldman, Anita Kafai Wong and Andrew Biro challenge the validity of the billing restrictions imposed by the Commission. The Court found the Measures issued by the Commission inconsistent with the provisions of the Constitution; therefore, it decided the measures have no force or effect – Deborah Judith Waldman v. The Medical Services Commission of British Columbia and The Attorney General of British Columbia (Respondents). Docket: A952722 & A961607.

¹² Author's translation to: "O caso Waldman versus The Medical Services Commission of British Columbia, ou simplesmente Waldman, foi uma disputa judicial que chegou à Suprema Corte da Columbia Britânica e envolvia uma política relacionada à força de trabalho em saúde. Ainda que tenha se desenvolvido no âmbito provincial, ganhou notoriedade no campo do Direito Sanitário. A Comissão de Serviços Médicos da Província da Columbia Britânica tinha a competência de definir a taxa de serviços que profissionais médicos deveriam responder no exercício de suas funções. Três médicos contestaram na justiça a metodologia que a comissão escolhera para calcular a taxa de cada médico, que era baseada em critérios de local de atuação." (Aith 2020, 333)

Another important case is the regulation of the voluntary health insurance market. In a 2018 report on voluntary health insurance (VHI), the WHO analyzed studies on the systems of different countries and eventually warns of the negative effects that voluntary health plans can have on Universal Health Coverage (UHC):

There is no set threshold of a VHI share as of total health expenditure that would hinder countries' efforts to move towards UHC. Nonetheless, it is crucial to be aware of VHI (expenditure) trends and to address potential challenges deriving from changes in VHI expenditure (World Health Organization 2010). Given the many risks and potential spill-over effects to the rest of the health system, VHI needs to be managed and regulated in such a way that it contributes to equitable progress towards UHC, or at least does not harm such progress (Mathauer & Kutzin 2018, 1)

Therefore, it is already known that voluntary health insurance should be regulated to contribute to universal access or, at least, to avoid the impairment of its progressive securement.

The three cases mentioned above (introduction of new technologies, training of health workforce, and voluntary health insurance) represent important components of national health care systems and impose major regulatory challenges for most countries. In addition, they show the importance of a global health analysis that goes beyond comparative research. Challenges of global dimension emerge from the dynamics of health workforce migration, the limited capacity to produce medicines and purchase them from a limited number of industries, and the economic power of multinational insurance companies (which are usually owners of healthcare establishments). These are just some examples, as the regulation of other private sectors demands data and research through the lens of human rights and global health. In fact, enforcing the right to health is expected to increasingly demand greater reflections on interrelated, complex themes and systems.

Conclusion

It is evident that, at least at this moment, health rights litigation reached exhaustion as a strategic instrument for enforcing the right to health in public-private health care systems. The effective enforcement of the right to health depends to a large extent on building good health care systems that prioritize equity, which interestingly several countries have shown it is independent of health as a right expressly stated in legal documents. In other words, it is apparent that health as a right experienced by all stems more from a state of cultural and civilizing progress in the country than from introducing a legal norm into the legislation or the Federal Constitution.

It is essential to establish a new set of research and discussions related to Global Health *and* Economic Law. It is a matter of prioritizing and systematizing the legal-regulatory knowledge of

health markets and public-private partnerships, with a view to identifying and understanding the best instruments for promoting equity and enforcing health as a right in the different health care systems worldwide while considering the political and economic strengths of Global Health. It is also a matter of expanding and developing the ethical-normative field of private health regulation.

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