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Abstract

Recognizing law as a determinant of scarcity in health care is vital. This paper underscores the need for a comprehensive approach to manage scarcity beyond intellectual property, using targeted regulations to promote affordability and counter market distortions. I argue that relying on law solely to ensure democratic deliberations for resource allocation overlooks market failures and economic inequalities that contribute to scarcity. I examine different "legal determinants of scarcity" that can be used, on the basis of the right to health, to improve or positively influence the availability and affordability of health technologies through complementary policies such as direct price control, competitive procurement, competition laws, and public-private partnerships. I conclude by asserting that health care affordability must be a central positive human rights obligation in economic and health policies and that states must strive to diversify their approaches to eliminate persistent economic barriers.

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Introduction

In global health, the burden of scarce resources has been a dominant discourse to justify differential treatment among patients with different health care needs.[1] In the name of scarcity, policy makers have to prioritize, and they prefer interventions that attain thresholds of cost-effectiveness and value considerations. Consider, for instance, patients in need of dialysis: due to the prohibitive costs of dialysis, health economists recommend that most health systems deprioritize this group of patients, generally forcing lower-income countries not to invest in this therapy; meanwhile, such rationing for dialysis is less frequent in wealthier states.[2]

The notion of scarcity has driven selective exclusions in the allocation of health care, but this is a reality that may be remedied by political choices.[3] Under the International Covenant on Economic, Social and Cultural Rights (ICESCR), states are obliged to use the best of their capabilities to maximize resources and pursue policies that promote the affordability of health care.[4] That includes not only existing budgets and financial resources but any other available measure, including legislation, to enable the progressive realization of rights.[5] This positive obligation is effective even in the context of extreme scarcity, such as public health emergencies, where states need to adapt policies to use all their capacity, including the authority to regulate private actors to respect, protect, and fulfill the right to health.[6] In addition, efforts to fulfill the right to health must be designed in accordance with human rights standards, such as affordability (or economic accessibility, a subcomponent of the long-accepted right to health framework of availability, accessibility, acceptability, and quality).[7]

However, human rights scholars (notably within this very journal) have framed the right to health as a right to a fair deliberation about the resources that exist in a given moment, and not primarily as a way to redress unfair market conditions that are the very reason that health systems are forced into painful resource dilemmas.[8] To shift from scarcity determinism, this paper articulates the notion of "legal determinants of scarcity" in health care and how such determinants should be harmonized with a socioeconomic rights framework that places affordability (or lower costs) at the center of health care policymaking in access to health technologies (e.g., vaccines, medicines, medical devices, and other health products). By "legal determinants of scarcity," I mean laws that influence, whether positively or negatively, a policy for resource availability (e.g., taxation) or that serve as a precondition for a policy that can minimize scarcity (e.g., a competitive procurement system that is not prescribed by law).[9] This concept could be applied to other economic factors in health care scarcity that are manageable through regulation (e.g., availability of the workforce, organ donations, or access to telemedicine), but this paper will examine only health technologies, where intellectual property (IP) normally remains at the center of human rights debates.

For general economic and social rights practitioners, the goal of resource mobilization and affordability may sound more intuitive, but in the global health and human rights community specifically, this stance is not common. Lawrence Gostin et al. have argued that legal determinants of health involve laws focusing primarily on public health outcomes and not exactly on the generation of more resources, so reframing them with an economic and social rights framework is useful for departing from the scarcity mindset and enhancing advocacy efforts.[10] Gostin et al.'s concept of legal determinants of health consists of any legal instrument that can be used against the "underlying social and economic causes of injury and disease," but the economic reasons for low levels of access to health care and health technologies that undermine population health, including market failures and poor price control, do not have a dominant place in their agenda.[11] Although the Lancet Commission's main

report on the legal determinants of health does briefly mention public-private partnerships (PPPs) and IP issues, the reference is made within the context of law and governance and not primarily in order to dismiss unnecessary rationing.[12] In general, scholars have not fully addressed the options available for improving affordability other than promoting exceptions or "flexibilities" to patents, even though affordability is mentioned as one objective of the legal determinants.[13]

With a rhetoric that unconditionally accepts scarcity rather than challenging it, the World Health Organization report *Institutionalizing Health Technology Assessments: A How to Guide* seems to be incompatible with the progressive realization of economic and social rights. The guide provides recommendations in which rights are regarded as troubling advocacy tools that may derail priority setting and in which public laws should instead be used mainly for ensuring compliance with rationing decisions.[14] Under this skeptical view of the transformative power of human rights, the right to health is not "universal" and should be limited to just "a reasonable set of public services."[15] Nothing in the report examines how law can also be a determinant of affordability and resource mobilization during priority setting. Similarly, the World Health Organization report on value-based health care falls short of presenting affordability as a main pillar of access to health care and focuses more on the quality, cost-effectiveness, and equitable distribution of a set of patient-oriented health benefits packages.[16]

To counter this narrative, we must reframe law as a determinant of health by embracing an economic and social rights approach against the mantra of scarcity in global health. Thus far, the closest advocacy around legal determinants of scarcity has been tied to the IP regime, where there is an established record of human rights mobilization. Yet patents are not the only reason that health care is unaffordable. Realizing the right to health must include other policies beyond exceptions to patents, despite the challenges inherent in building rights claims around complex economic processes of market regulation. To this end, this paper explores some key complementary policies that have been underemployed as part of states' obligation to maximize resources established by article 2 of the ICESCR, identifying a range of legal determinants of scarcity (beyond IP laws) that influence the price of health technologies. These complementary policies, which are listed in the 2020 *WHO Guideline on Country Pharmaceutical Price Policies*, are direct price control, price negotiation and contractual mechanisms, competition laws, and PPPs.[17]

Below, I begin by exploring the need to broaden the scope of the legal determinants of scarcity in areas other than IP. I then illustrate the application of legal determinants of scarcity, demonstrating their capacity to be accepted as a human rights concern in areas such as price control, procurement, competition laws, and PPPs.

The disproportionate attention to IP advocacy

Traditionally, to address concerns of affordability and maximum resources, human rights scholars have advocated for the reform of domestic and international IP laws.[18] This section will demonstrate that policy makers and patients should explore other routes such as those listed in the World Health Organization's pharmaceutical policy guidance, including price control and procurements laws.[19] This section argues that legal determinants of scarcity are indirect or circumstantial to health affordability. Therefore, they are not a guarantee of affordability of health care; instead, they have to be carefully customized among many options to minimize potential downsides.

To begin, the dissatisfaction with IP laws among human rights practitioners has been evident since the 2000s, with General Comment 14

and the United Nations Sub-Commission on the Promotion and Protection of Human Rights' subsequent resolution on intellectual property rights and human rights, followed by a continuous cycle of other similar texts issued at the United Nations level reiterating the need to flexibilize IP laws in the face of health needs.[20] A similar discussion followed with respect to article 15(1)(b) of the ICESCR (access to science), which, it can be argued, prevails over patent holders' rights to property.[21]

Accordingly, the overdominance of IP as a barrier to realizing the right to health is equally salient in international political dialogues on drug affordability. During the United Nations Secretary-General's High-Level Panel on Access to Medicines, most of the external submissions revolved around IP policies. Exceptions were some allusions to competition laws, negotiation power, and local product development.[22] France complained about the IP focus of the consultation procedure, affirming that "by reducing the scope ... the panel significantly limits its methods and conveys a limited interpretation of issues affecting access to medicines."[23] The Secretary-General's final report also places a strong emphasis on IP, as if all costly drugs were the result of the failures in IP regimes. Alternative policies are seen only in terms of permissible measures to supplement the patent system (for instance, raising competition issues as a subfield of the regulation of non-patented drugs).[24]

Few at the United Nations level have linked other policies to laws that promote affordability more holistically. In a major exception to the IP focus, former Special Rapporteur on the right to health Anand Grover produced, in 2013, one of the most comprehensive reviews of the alternative policies open to states to ensure the affordability of medicines, mentioning direct interventions in the market such as price control and competition laws.[25] However, the report falls short of indicating that there is an immediate obligation to reform legislation or regulatory frameworks on other forms of price control, as human rights practice has required for IP laws. Disappointingly, human rights discourse remains narrowly focused on IP. For instance, in the aftermath of the COVID-19 pandemic, calls from human rights bodies have been focused mainly on relaxing IP rules to promote access to new vaccines and drugs.[26]

This dogmatic vision does not recognize that, in many cases, supporting legal tools should be introduced. Empirically, IP flexibilities—exceptions to IP provisions for public health reasons, such as compulsory licenses of patented pharmaceuticals or parallel imports of generic versions—may not bear fruit.[27] In the case of compulsory licenses, such a measure has succeeded in only a few cases, predominantly for HIV treatments (and without comparing what could be achieved by a combination of other policies).[28] To make matters worse, compulsory licenses may result in negative impacts on affordability, despite frequent support from academics.[29] Ideally, just signaling the possibility of a compulsory license can persuade a producer to cut prices, particularly where countries already benefit from local industrial power or have access to external generic makers.[30] In practice, research has shown that the potential discounts are not as great as when there is a combination of other policies (as experienced by countries with the highest savings, particularly when producing locally is more expensive than procurement abroad).[31]

These hurdles are even more challenging for developing countries, where human rights advocacy has persistently warned against IP laws. For the poorest countries, economic models often predict that instruments such as compulsory licenses will not be successful. Pharmaceutical companies and exporting states can exercise political pressure for IP implementation or, in the case of suppliers, blackmail a country with market withdrawal or exclusion from new research.[32] Examples of proposed

compulsory licenses that in fact generate price reductions are generally from countries that are able to threaten the patent holders with local production or another supplier.[33] Countries without access to products manufactured in the Global South may be left with the only alternative of the Doha Declaration to import from high-income producing countries (with Rwanda being reportedly the only case of that so far).[34]

Frontiers of law to challenge scarcity as a barrier to realizing the right to health

Access policies for health technologies imply some legal basis and do not operate outside the scope of law, administrative authorizations and competencies to control excessive prices.[35] Some of these legal determinants of scarcity arise in the price environment and not at the research and development (R&D) and patents level, where human rights scholarship is traditionally focused.[36] For instance, the unaffordability of patented and non-patented products requires intervention in the pricing environment (the moment at which technology producers set their prices or profits).[37] Some of these regulations are "semantic flexibilities," measures allowed in the IP regime under domestic laws or not specifically prohibited by the Agreement on Trade-Related Aspects of Intellectual Property Rights (e.g., price controls or a doctrine prohibiting excessive prices).[38]

This section reviews some of those complementary frameworks found in the *WHO Guideline on Country Pharmaceutical Price Policies*, such as direct price control, price negotiation and contractual mechanisms, competition laws, and PPPs.[39] These represent neglected areas that have rarely been addressed as a right to health concern. The conceivable right to health advocacy may vary for each policy at hand: some advocacy efforts could focus on judicial interpretation (e.g., competition laws), while others might be more conducive to extrajudicial campaigns, legislative action, and political influence to establish an adequate regulatory environment for promoting access to health technologies (e.g., PPPs).

Direct price control

An intuitive tool that can be incorporated by human rights advocacy is to call for laws and regulations that directly control pharmaceutical prices. This intervention consists of regulatory techniques generally used for pharmaceutical markets, but price controls can be used for any aspect of health care, including health insurance. Even in the United States, which embraces a predominantly free-market model, there are laws to protect the uninsured from overcharges in hospitals.[40] Many countries have introduced price regulation through different legal formulae and institutions: some have national agencies mandated with dictating the prices of patented drugs (e.g., Brazil and Canada), and others also have arrangements at the regional level (e.g., Canada, with a coordinated generic price control).[41] For pharmaceutical products, the two most common forms of price control are price markups (or price caps) and reference pricing, which imposes values of reimbursement for different categories of drugs to stimulate lower spending for health services or to induce the industry to mark down its products.[42]

Given the nature of international obligations (which ordinarily adopt a state-centered approach), it would be subject to debate how much human rights could be effectively employed to enforce direct price control on private for-profit pharmaceutical companies (though, as mentioned before, states must deploy their regulatory power to maximize resources). However, there are possible legal pathways through local jurisprudence and constitutional developments that could serve as a lesson and inspiration for future activism. In contrast

to international law, some jurisdictions impose horizontal obligations on private actors, providing a legal opportunity to invoke the right to health against excessive prices.[43]

One record of a more progressive usage of the right to health in private contractual relations to enforce price control is a line of jurisprudence built by the Brazilian Supreme Constitutional Court. In awarding an interim injunction to suspend the increase of up to 40% for private health insurance under new regulations of the national health insurance agency, Justice Carmen Lúcia stated in 2018 that "healthcare is not a commodity," "life is not a business," and "dignity is not profit."[44] Similarly, Justice Marco Aurélio intervened in 2018 against excessive price readjustments for elderly users of private health insurance as a practice incompatible with the right to health under the domestic constitutional system. He noted that private contracts are governed by the right to health, and thus the state may exercise its regulatory power to pursue public interests: "Health promotion, even in the private sphere, is not linked to profit assumptions … The health insurance lucrative market cannot flaunt the importance of this social service, recognized in Article 197 (right to health)."[45]

The effectiveness of price control policies in promoting health technologies may depend on their careful management. For instance, in 2016, the Colombian Constitutional Court rejected a constitutional complaint against a national statute that empowered the government to regulate the prices of health care products, deeming such regulations consistent with the right to health.[46] Nevertheless, Colombia's experience with price regulation has yielded mixed results. While pharmaceutical costs have decreased by 43%, there has been a doubling of government public health expenditures through more purchases.[47] The success of price regulation may hinge on factors such as thoughtful drug administration but can equally depend on more resources to meet an extraordinarily pent-up demand of previously neglected patients. The positive impact can vary depending on the specific drug, as seen in the case of over-the-counter contraceptives in Colombia, where price regulation has led to improved access.[48]

Negotiation and procurement

While laws may impose direct control over prices, they can also create conditions whereby governments can negotiate for discounts on retail prices of a health technology. Contractual relations have rarely received attention as a human rights concern, with the notable exception of cases involving health care corruption.[49] However, other regulatory factors may also affect the use of resources through price negotiation, transparency, and rules of procurement.[50]

First, there is great scope for advancing the negotiating powers of governments in health care, as not all countries have a policy of price negotiation.[51] The United States had been lagging in this regard until 2022, when it partially removed legal restrictions that had prevented the federal government from negotiating pharmaceutical prices in one of its public coverage programs.[52] In other countries, such as France, government regulations allow greater negotiation powers than in the United States, particularly if new medications do not provide significant additional benefits.[53] Similarly, developing countries have sustained access to medicines by continuous negotiation, as demonstrated by Brazil's HIV program (though this policy may be less effective in countries lacking institutional capacity or bargaining power).[54]

In August 2022, the Inflation Reduction Act was signed into law in the United States, introducing limited powers to secure price deals for selected prescribing medicines.[55] These reforms target users of the federal program Medicare, who are people aged 65 and over. In addition to capping out-of-pocket expenses and holding pharmaceutical companies accountable for price hikes exceeding

the inflation rate, the legislation is anticipated to yield substantial government savings. Potential negotiations could result in savings between US$16.0 billion and $28.3 billion, depending on the selection criteria, as approximately 60 new drugs may be eligible for the program by 2029.[56] This new law has been criticized by corporations, which argue that it breaches the right to property, suggesting that health advocates should also engage human rights in price negotiations.[57]

Another determinant of the negotiation environment is price transparency. This requirement can be imposed by laws in many forms: for example, by prior notification of a planned increase or a report about new drugs approved in a market.[58] Transparency is also related to access to information on how the price is fixed in other markets. Where prices in other countries are public, states can benchmark between markets.[59]

Moreover, it is not only the possibility of negotiating that stimulates affordability; correlated procurement laws can also ensure lower costs.[60] Comparative analyses of procurement policies in different countries suggest that a combination of factors—such as centralized purchasing, transparency of pricing in markets, corruption control, strong auctioning models, price benchmarking, or preference for generic products—results in better deals.[61] Conversely, a badly designed procurement process can result in gains in one tender being annulled by losses in another contract for similar drugs, as experienced in Belgium.[62]

In such negotiations, certain clauses are directly linked with affordability. Conditional contracts for new technologies are denominated management entry agreements (MEAs), setting out the expected delivery, budget, or clinical outcomes in order to clarify uncertainties and guarantee lower costs. Clauses in MEAs are variable and may offer different avenues to balance access to technology with reduced costs, while sharing the risks between the government and manufacturers for specific goals: for example, budget control; safety monitoring, clinical efficacy, and cost-effectiveness; or usage and distribution of a technology.[63]

MEAs remain a strategy mostly undertaken in developed countries.[64] Part of this is due to the fact that MEAs tend to favor emerging technologies for expensive treatments or new advancements by orphan drugs, cancer, and other applications with low cost-effectiveness. Another explanation is that developing countries do not hold the same level of preparedness to negotiate and bargain the terms of the contract—unless encouraged by an acute crisis, such as in the world battle to ensure early HIV treatments. Few countries have adopted this model systematically, but Italy has exhibited significant savings in health care in doing so (€192 million in 2022).[65] As developing economies, Colombia and Brazil have also considered adopting these contracts, particularly because of the enforceability of the right to health, which may determine the mandatory supply of new technologies before all evidence of performance has been produced.[66] While additional research with empirical data is being undertaken, MEAs may offer a way to demand price discounts until the suggested public health savings are confirmed.

Competition laws

Designed to regulate market abuse and price distortion, competition laws may sometimes be applied against the pharmaceutical industry in a way that facilitates access to new technologies. However, countries may be unable or reluctant to enforce a more competitive market due to circumstances such as methodological barriers to determining excessive prices and a lack of transparency and access to data relating to the items that make up the costs of health care products.[67]

In developing countries, competition laws in general have only recently taken effect, and, despite some good progress, many countries still have little practice in the field and face difficulties in investi-

gating, identifying, and prosecuting misconduct.[68] Even though there are some successful cases, they may still be articulated without human rights language, and many countries may not directly address price profiteering in the pharmaceutical market.

The challenges of prosecuting companies for price gouging are experienced by developed countries as well. In the European market, historically, European Union law has not been well suited to challenge unaffordability as a sign of unfair pricing and has been timid in considering substantive human rights in competition laws.[69] In European Union case law, definitions of value and fairness have been rather muddled in examining excessive pricing (this concept also being ambiguous), and competition authorities have made little difference.[70] In the past few years, there has been a notable resurgence of interest in using the competition framework to combat market distortions resulting from excessive pricing. The first such investigation was initiated in 2017, focusing on Aspen.[71] The European Commission ultimately reached an agreement with the manufacturer in 2021. Under this agreement, Aspen committed to legally binding price reductions averaging 73% for six off-patent cancer drugs.[72]

Another example of increased attention to competition as a tool to address excessive prices comes from South Africa. The country had an early precedent of resorting to competition laws strategically during the early 2000s, in a critical time of the HIV pandemic, bringing a pioneering challenge against a patent holder. In 2003, an agreement was reached with GSK (formerly GlaxoSmithKline) and Boehringer Ingelheim to withdraw prosecution for excessive prices of antiretrovirals before a competition tribunal.[73] Under the settlement, the companies authorized generic licenses and restricted their royalties to 5% of the net sales. Two decades later, the South African Competition Commission finally turned against another patent holder for excessive pricing by investigating Roche, producer of the oncological drug Herceptin.[74] The case is still pending but demonstrates the more active stance of the South African authorities to inspect the market after passing an amendment to the domestic competition legislation in 2018 enhancing investigations into excessive pricing.[75] With these reforms, the burden of proof rests with the accused company to demonstrate reasonable pricing, if it is found to be in a dominant market position.[76]

In such cases, even though competition laws could be associated with human rights violations, a human rights framework is yet to be established more comprehensively in the literature and further espoused by advocacy. Kwanghyuk Yoo has recently advocated a connection between the right to health and competition laws, considering the context of the pharmaceutical market of the United States and alluding to issues of market abuse by intermediaries and collusion between brand owners by purchasing the right to delay the production of generic suppliers.[77] However, such views are centered on business and human rights guidelines to regulate business actors and thus lack enforceability since they are not binding legal obligations.[78]

Public-private partnerships

PPPs address one type of scarcity—a lack of scientific projects, local technology development, and private investment—that could eventually lead to lower prices of new health technologies if coproduced or managed by public and private entities. The success of PPPs may require specific supporting laws that authorize and govern the delegation of public services or that provide more safeguards for the parties involved.[79] Projects in countries without specific legislation on PPPs may not perform as well as others with adequate legal provisions.[80] Currently, specific PPP laws appear to encourage more investment in countries where other procurement laws and institutional capacity do not offer certainty and flexibility to attract private financing.[81]

One field where PPPs have shown great potential is that of biosimilars. This type of treatment is a product very similar to another biological technology (substances produced naturally by organisms, such as animals and humans). The technology used to make these compounds is far too complex to be employed in some countries (particularly because of safety issues or lack of clinical data).[82] To find a way through this, PPPs can promote cooperation to build domestic capacity around technologies that will reduce the cost of producing biosimilars.

In Brazil, PPPs have paved the way for an exceptional trail of local innovation, acknowledged by the World Health Organization Council on the Economics of Health for All as a prominent model showcasing the reconfiguration of the economic landscape in support of public health interests as a common good.[83] Many of the technologies made available were previously pariahs in the massive right to health litigation against the state, as they would not be cost-effective or affordable for the government. While Brazilian PPPs were not overtly motivated by litigation, they do exhibit a certain connection to the prevalent number of lawsuits, as they represent a policy that has enhanced state capacity in sectors subject to substantial judicial scrutiny, thereby hinting at a developmental agenda. Such an increase in state capacity has been argued as a desirable effect of court interventions.[84]

Yet guidance on how to steer the right to health toward access to health technologies may still overlook the impact of PPPs. In relation to long-term kidney therapies, Diya Uberoi and Lisa Forman's analysis, for instance, underscores the potential of the right to health in facilitating patient access through legal actions and rights-based advocacy but fails to adequately acknowledge the role of PPPs in this context.[85] These contracts, though, may offer alternative means where direct litigation has failed (see the famous case of *Soobramoney*, in which a South African court upheld refusing a treatment for a renal patient).[86] In North Ethiopia, before a pilot with a PPP was launched in 2013, local hospitals could not offer kidney treatments, including hemodialysis.[87] While this policy alone cannot fully dissipate cost pressures, since then, the PPP legal framework in Ethiopia has been further developed as a strategy of the Ministry of Health, and new agreements have expanded access to kidney treatments in other hospitals.[88]

Conclusion

The central contention in this paper has been that, under the right to health, states have the obligation to apply legislation that optimizes market conditions, such as price formation, so as to privilege affordability. In many jurisdictions, alternative policies that could enhance affordability are denominated just as "legal barriers" or lack of "legal input" or necessary regulation, while they should be considered a failure of the right to health implementation by not adopting necessary laws.[89] Policy makers and human rights experts share a common tendency to look at affordability narrowly as a matter of IP laws, which has limited the range of rights-based approaches to legislate against scarcity. As a result, in comparison to removing IP barriers, such additional legal tools, from price control to competition laws, remain marginal in human rights mobilization.

These correlated policies (under the umbrella term of legal determinants of scarcity), however, cannot provide a "one size fits all" response to specific questions related to local development and market behavior. It is important to establish in each case—with targeted research in collaboration with health economists and pharmaceutical policy analysts—what the specific measures are that are most likely to create the right mix of regulation for each health care service or good. This will also contribute to the state being able to satisfy the reasonableness test by showing the meaningful steps it has taken toward the implementation of the right to

health through improving the legal environment.

Appreciating the existence of legal determinants of scarcity and broadening the human rights agenda is pivotal to integrating substantive policies with fair deliberations for priority setting. As Livio Garattini and Anna Padula note, "prices can hardly (if ever) be really right in a 'market failure' context."[90] Consequently, procedural approaches to the right to health focused on priority setting will not fully engender the realization of the right to health unless the underlying causes of scarcity are duly confronted.

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