The editors of *Revista del Hospital Italiano de Buenos Aires* offer our readers the opportunity to reflect on topics currently under debate within the scientific community. To that end, we have invited two renowned experts with opposing views on the coverage of high-cost medication to present their perspectives based on a hypothetical clinical case. Below, we share the reflections of Dr. Carlos García and Prof. Florencia Braga Menéndez based on the following hypothetical scenario:

> *The health official of a locality receives a request for coverage of a high-cost medication for the treatment of a degenerative disease in a 4-year-old child. The medication is under consideration for approval by the United States Food and Drug Administration (FDA) and has demonstrated that it is safe and significantly delays developmental regression by four months; however, it does not alter the poor long-term prognosis of the disease.*
> *The community is deeply affected by the family's situation, and the media is closely following any updates related to the case.*

High-Cost Treatments: Resources Are Not Infinite

Carlos E. García

Director del Programa GESIS, Dirección y Administración de Servicios de Salud del Instituto Universitario Hospital Italiano de Buenos Aires. Investigador Asociado del Departamento de Calidad, Seguridad del Paciente y Gestión Clínica del Instituto de Efectividad Clínica y Sanitaria (IECS). Jefe del Departamento de Atención Ambulatoria del Hospital Italiano de Buenos Aires. Buenos Aires, Argentina

This case presents a relatively common situation for public health. The proposed medication, as it is "under consideration" for approval by the safety agency, has already passed through the various stages of clinical research. Therefore, it has proven to be safe and to have relative efficacy, meaning it does not cause severe side effects, and compared to those who do not receive it, it has provided an objective improvement by delaying the deterioration of developmental abilities, maintaining functionality for an additional four months.

However, other aspects help decision-makers approve and bear the cost of the treatment:

1. Is the treatment cost-effective?
2. Can the community afford it?
3. What is its opportunity cost?

The answer to the first question requires a rigorous cost-effectiveness analysis that objectively expresses the cost incurred to achieve specified outcomes, which can be measured in natural units, such as years of life gained or deaths avoided, or in more complex measures like Quality-Adjusted Life Years (QALY) or Disability-Adjusted Life Years (DALY).

However, there are still two fundamental steps to approve its use: determining whether the insurer can afford the expense or budgetary impact analysis and assessing the opportunity cost. Since money is a finite resource, what goes to a specific budget "silo" is no longer available to others. The impact of incurring this expense in an impoverished society with high infant mortality rates due to malnutrition, for example, would be very different compared to a wealthy society where all basic needs are already covered.

In Figure 1, taken from Augustovski (2002), a method for categorizing the results of economic evaluations is presented, expressing outcomes in terms of incremental costs and treatment effectiveness. Our example presents a situation of high incremental cost (the cost of the medication) and only marginally

Author for correspondence: carlos.garcia@hospitalitaliano.org.ar, García CE.

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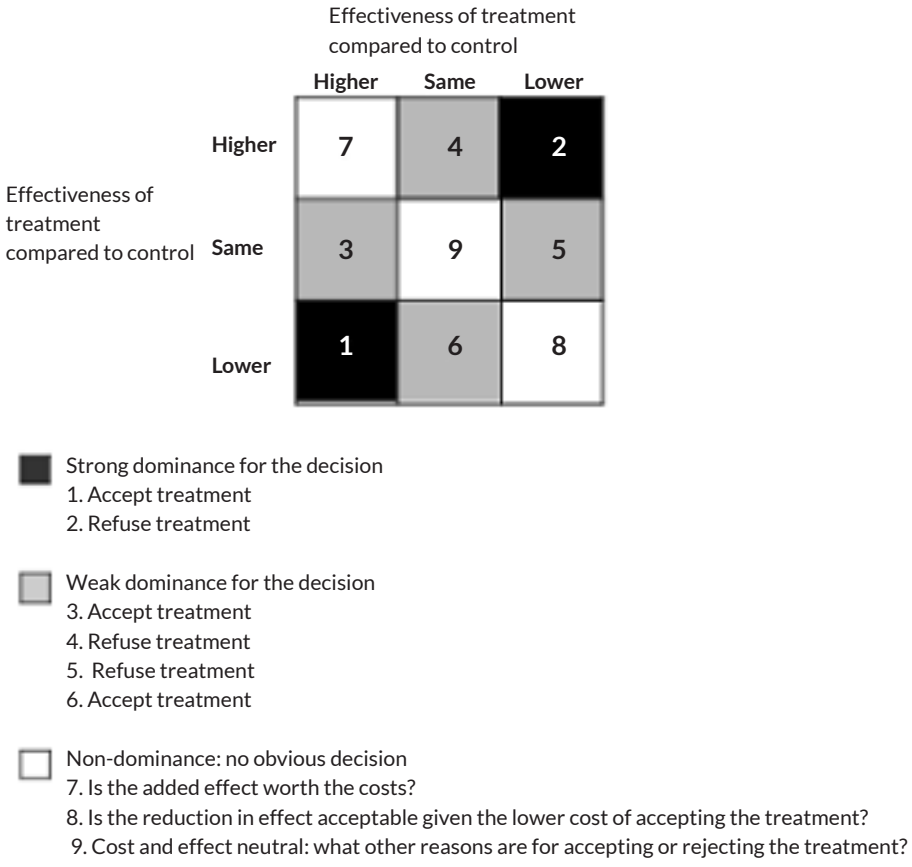

greater effectiveness (a mere 4-month delay in the loss of developmental milestones). In this case, the budget impact and opportunity cost incurred by administering the treatment would tip the scale towards not authorizing the medication. The scenario posed by this case is an example of situations that are increasingly common in real life. The decision-making process posed ex post facto becomes extremely difficult due to the asymmetry of rationality on the part of the decision-makers and stakeholders.

Quite frequently, these cases are brought to court, sometimes covered by the media, and an injunction results in a ruling favoring the coverage, ultimately bypassing all the elements of rational decision-making.

In conclusion, in this type of situation, which is becoming increasingly common due to the constant emergence of high-cost medications, decision-making must follow rational principles that take into account all aspects of coverage, including cost, the effect obtained, budgetary impact, and the opportunity cost incurred by covering the treatment. Therefore, it is crucial that these decisions be handled by public authorities and, whenever possible, guided by 'ex-ante' frameworks that employ objective tools to support the decision-making process.

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High-Cost Medications: A Human Rights Issue for Global Public Health

Florencia Braga Menéndez
Directora de Proyectos en ALAPA, Alianza Argentina de Pacientes. Buenos Aires, Argentina

In the complex world of contemporary healthcare, one of the most pressing and controversial challenges is access to high-cost medications. These treatments, often innovative and revolutionary in their effectiveness, also pose a significant burden on the individuals who need them and the healthcare systems that must finance them. Amid ethical, economic, and political debates, a crucial question arises: How do we ensure that patients receive the medications they need without jeopardizing the financial sustainability of healthcare systems?

The swift advancement in specialized medication development has contributed to rising costs, primarily driven by the financial burdens of research, development, and marketing. This rise has created a gap between availability and access, with many patients struggling to afford the high prices of life-saving treatments. From rare diseases to chronic conditions, the financial burden of these medications can be overwhelming, leading to difficult choices between health and financial stability.

For healthcare systems, the challenge becomes even more pronounced. The need to ensure equitable access to effective treatments is at odds with the constraints of limited budgets and increasing demands. High-cost medications can disrupt public health budgets, forcing decision-makers to engage in financial juggling to meet the needs of the people. This dilemma is further exacerbated by the rapid evolution of medical science, with new treatments entering the market at a dizzying pace, each one priced higher than the last.

The issue of access to high-cost medications also raises ethical questions about equity in healthcare. Should access to health depend on the ability to pay? Or should it be a fundamental right guaranteed for all, regardless of their financial situation? These questions underscore the necessity for a worldwide and cooperative strategy to tackle the issue - one that transcends economic factors to incorporate social justice and human rights.

The equity we thought was assured by the universal human rights charters of the mid-20th century is not genuinely guaranteed for all. The understanding of health when those declarations were established is not the same as the health issues we address today; it was not the health of the post-genomic era, not the health proposed by precision medicine, and it was not the expensive health offered on the market today. The task, then, is to ensure that this new, precision medicine reaches every corner of the planet.

In response to these challenges, various stakeholders are exploring innovative solutions. Governments and international organizations are negotiating lower prices with pharmaceutical companies, utilizing strategies such as collective purchasing and compulsory licensing to make medications more affordable. Additionally, alternative funding models are being promoted, such as pay-for-performance agreements that link payments to the clinical effectiveness of treatments. Public production of medications, overall improvements needed in the unification of ineffective fragmented national health systems, early diagnostics, telemedicine, and digitized medical records, repositioning approved drugs for new uses, declaring all chronic diseases as Notifiable Diseases (ND) and subsequently creating patient registries for these conditions to build reliable epidemiological information, unified treatment guidelines endorsed by various medical societies, regional consolidated purchasing of medications, and strengthening policies for the production of bioequivalents in biological drugs are all organizational strategies that could make the health system more efficient and viable.

But it always seems easier to deny medications, delay diagnoses, cut dosages, undermine patient adherence to their treatments, burden them with new bureaucratic obstacles, "kick the can down the road," and pass the issue on to the next government.

That is how we have reached a situation where we only achieve the judicialization of health, forcing medications to be purchased urgently and at much higher prices to comply with court orders following a judge's intervention.

Author for correspondence: florenciabraga@alianzapacientes.org, Braga Menéndez F.

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Innovation in how medications are developed and financed is also underway. The move toward more collaborative and transparent approaches in research and development, such as open research and open access to data, has the potential to accelerate the discovery of new treatments and reduce associated costs. Similarly, promoting competition and implementing value-based pricing policies can help curb disproportionate price increases.

What should never happen is that patients receive the argument of the "short sheet," which states that if it covers your feet, it leaves your head exposed. We are tired of holding patients who receive expensive treatments responsible for the lack of coverage that will subsequently affect hundreds of healthy patients who will not be able to receive, for example, their vaccinations.

The hypothetical case presented to us, the young child with a neurodegenerative disease that we are discussing, vividly illustrates the ethical and emotional complexities involved, raising uncomfortable questions about the value of life and the limits of what we are willing to do to protect it. On the one hand, there is the hope that this medication might provide some relief, however minimal, from the suffering of the child and their family. On the other hand, there is the economic challenge of delivering a treatment whose exorbitant cost could jeopardize the financial stability of the family and the healthcare system that supports it. The imperfect response that some systems have given to this debate is the intervention of Health Technology Assessment (HTA) agencies; these agencies present various scenarios where the cost/benefit relationship of each treatment related to each particular case is considered: "What if the expensive medication is needed by someone who is in prison for monstrous crimes?" "What if the medication in question will only extend life by a few months and the patient is over 80 years old?"

Patient organizations oppose these proposals, which we consider dangerously perverse, and we demand that the variable be price and negotiations with payers, never patients; and we deliberately say PRICE, not COST, because the actual investment that went into the development of a particular medication is not known; we know the price, but not the production cost. The industry talks about gigantic investments in developing new drugs; nevertheless, that cost is not borne solely by the pharmaceutical industry, as many actors are involved in the chain that goes from basic research to translational research to mass production and the market launch of a particular medication. Along the long road of technological transfer that ends up in our hands in a blister pack of pills, many actors share the production cost, including research universities, families, and governments. That is why we patients want a law similar to the Sunshine Act established in the United States to ensure transparency in the relationship between the industry and prescribing physicians (a relationship historically marked by bribery and unethical incentives) to clarify the actual production cost of medications.

How do we balance the need for innovation and the incentive to develop effective treatments with the responsibility to ensure those therapies are available to everyone who needs them, regardless of their ability to pay? As we have already stated, many strategies are available if we make the ethical-political decision to support the patient.

The perspective of the Alianza Argentina de Pacientes (ALAPA) represents just one point of view in this evident tension: that of the patients and their families. From our perspective, it is clear that medication is a social good rather than a commodity, and all arguments aimed at preventing access must obey the needs of that single patient in a situation of need. Just as social minorities have managed to gain access to rights that were once unthinkable in the past fifty years, the strategy of expanding rights proposes that society should strive to adapt to the vulnerable person's fundamental need for treatment.

We do not deny the limiting arguments of reality but believe that if we want to uphold the rights guaranteed by the major Human Rights conventions of the mid-20th century, we must firmly defend the indispensability of finding a committed solution. That is a matter of Human Rights. Dying due to the inability to access treatment is dying from abandonment: it is MISTHANASIA, and if the entity responsible for this abandonment is the State, we would be talking about a crime against humanity.

The little boy in the example will probably end up dying due to the lack of support from various responsible actors, or perhaps the doctor who, "honoring their Hippocratic Oath," will finally sign the prescription for the medication the boy needs, will be fired from their workplace, a victim of PRECOMES (institutional coercive pressure on the prescribing doctor) from their superiors. In any case, an unhappy ending.

Above all, we must find solutions beyond merely addressing economic and logistical obstacles while upholding our moral duty to care for and safeguard the most vulnerable.

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