BREVE 13

STRENGTHENING GOVERNMENTS' CAPACITY TO DISCERN VALUE: THE NEED TO ADDRESS TECHNOLOGICAL PRESSURE ON HEALTH EXPENDITURE

Based on a presentation at CRITERIA by Alejandro Gaviria, Minister of Health of Colombia, December 2015

A series on policies and methods based on presentations for experts. Prepared by CRITERIA, a knowledge network on prioritization and health benefit plans from the Inter-American Development Bank.

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GLOSSARY OF ACRONYMS FROM SPANISH TO ENGLISH

CTC	Technical and Scientific Committee
EPS	Health-Promoting Entity
FOSYGA	Solidarity and Guarantee Fund
IETS	Health Technology Assessment Institute
INVIMA	National Institute of Food and Drug Monitoring
IPS	Health Care Provider Institution
MSPS	Ministry of Health and Social Protection of Colombia
OCDE	Organization for Economic Cooperation and Development
Non-POS	Technologies excluded from the Mandatory Health Plan
POS	Mandatory Health Plan (Colombian Benefits Plan)

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INTRODUCTION

This *Breve* presents the story of how, in recent years, the Colombian health system has struggled with technological pressure. The impact of technological pressure on the health sector during the last few years could be summarized by either of two phrases: "the cost of success" or "the adverse consequences of technological pressure."

This *Breve* describes how the inadequate incorporation of health innovations into the system can threaten an egalitarian-inspired reform that has brought social progress. The document also discusses the policy tools Colombia has introduced to face this technological pressure. A commitment to strengthening the government's capacity to discern[2] the value of health care innovations lies at the core of these policies.

1 The webinar and transcription in Spanish of this presentation may be found at the IDB Criteria Network: http://www.redcriteria.org/webinars/.

2 Definition of discern (verb): to distinguish or discriminate.

CHARACTERISTICS AND ACHIEVEMENTS OF A COMPLEX HEALTH SYSTEM

The first part of the story pertains to the context of the current Colombian health system. Its legal basis, Law 100 of 1993, provides for one of the most radical regulatory changes of a health system in the region; it transforms a national health system covering only a few into a multipayer system whose main objective is to move towards universal health care coverage for all Colombians. There are a number of specific actors at work within the health system: insurers or health-promoting entities (EPSs), which are responsible for the enrollment of members and the management of health services; health care provider institutions (IPSs), which are responsible for the provision of health services; and local authorities (i.e., departments and municipalities), which are in charge of managing public health.

The structure of this system is based on a mixed financing scheme, which relies on the contributions of citizens with the ability to pay and funds from general national and subnational taxes. There are two main health insurance regimes[3]: the contributory system, which covers citizens with formal jobs, and the subsidized system, which covers the vulnerable population and informal workers. Members of the subsidized regime do not make any periodic contributions. Enrollees of both regimes are entitled to the same benefit plan, known as the Mandatory Health Plan (POS). Unlike the system in other countries, the per capita allocation made to finance this plan is virtually the same in both regimes.

One of the pillars of the Colombian health system is the principle of **solidarity**[4], which means that a portion of the contributions to the contributory regime is channeled to the subsidized regime. Initially, in light of the country's economic transition, it was estimated that the number of formal workers would grow to represent two-thirds of Colombia's insured population; however, at present, enrollment figures from the Ministry of Health and Social Protection (MSPS) show that just slightly over half of insured individuals (52%) are covered by the subsidized regime. The imbalance of contributions vis-à-vis the projections, along with almost universal health coverage (97% of Colombians are insured) and equal access to the same benefit plan by both regimes, represents a huge challenge to the financial sustainability of the health system. How does the country finance a health system to which less than half of the population contributes on a regular basis?

3 There are other special regimes, such as ones for judges and for the military.

4 According to Article 2 of Law 100 of 1993, solidarity is the practice of mutual aid among people, generations, economic sectors, regions and communities, under the principle that the strongest help the weakest. Internal solidarity exists within the contributory regime in that those with the highest income pay more, while external solidarity exists in that a percentage of the contributory payment is destined to fund individuals in the subsidized regime.

Another complexity of the Colombian health system is its **dual decentralization**. The government delegates the coverage of services for individuals to the EPSs, while the delivery of community and public health services falls to local authorities (municipalities and departments). As a result, a complex decentralization has emerged under which the insurance functions for the individual provision of services are rendered through private, public or mixed agents, while public health functions are carried out by local public authorities. This situation has created significant challenges when trying to coordinate agents and align their incentives to achieve health outcomes without jeopardizing sustainability.

Similarly, the Colombian health system is **mixed in terms of the nature of its stakeholders.** Both insurers and providers can be of a private, public or mixed nature. In small municipalities (by population size), the provision of basic care tends to be mostly public, while private providers dominate the delivery of complex services in the departmental capitals and most urban parts of the country.

The system is also **mixed in terms of funding.** Payroll tax contributions finance nearly 52% of the insurance system (2010 to 2013), with the remaining 48% coming from different general taxes (Ministry of Health and Social Protection, 2013). Furthermore, Colombia is one of the countries in the region that has been most affected by the **judicialization of health.** The Colombian Constitution of 1991 created a Constitutional Court, together with mechanisms, such as the writ of protection, to protect fundamental rights, and it greatly enhanced the public's access to the courts through unfettered standing and lack of procedural requirements (Yamin & Parra, 2009). Initially, the 1991 Constitution did not proclaim health to be a fundamental right but rather an economic, social and cultural one; however, beginning in 1994, case law that granted access to health technologies not covered by the mandatory benefits package was developed in the name of the protection of the right to health, via its connection to the fundamental right to life, thereby establishing precedents to transform the right to health into an autonomous fundamental right. In 2015, these case-law provisions were codified in the Statutory Health Act[5], making health an autonomous fundamental right.

Considering health as a fundamental right means that in Colombia, when a citizen does not receive a requested health service and, thus, considers that the right to health has been breached, the individual can file a petition including the respective medical prescription before a judge, who then determines whether the health technology must be granted. This legal mechanism is known as a writ of protection, and it has been massively used in Colombia. For example, in 2014 alone, 118.281 writs of protection were presented in Colombia, according to information provided by the

5 The Statutory Health Act is a higher-order law that made structural changes, guaranteeing the fundamental right to health and establishing its regulation and protection mechanisms.

Constitutional Court (Office of the Ombudsman, 2015). In addition to the writ of protection, an expedited administrative path exists, allowing patients to request services that are not part of the explicit benefits plan through their prescribing physician. Each request is assessed by the **Technical and Scientific Committee (CTC)** of each EPS. The committee is made up of a group of doctors who decide if the requested technology is critical for the patient[6]. Services provided via a writ of protection or the decision of a CTC are funded with public resources from the health sector.

This last characteristic of the Colombian health system, which allows access to any technology not included in the specific benefits plan through the decision of a judge or CTC, deserves special attention because it has been the main entry point for new health technologies. As a result, it has become a kind of **reimbursement insurance** and/or a **benefits plan functioning in parallel to the POS.** This situation will be further explained below.

In summary, on the one hand, Colombia has the POS[7], an explicit health benefits package with previously defined inclusions based on epidemiological, cost-benefit and other considerations; on the other hand, there is a second *de facto* benefits package, which grows spontaneously and often haphazardly, as a result of accumulated court rulings or case-by-case decisions made by intermediary entities' CTCs or insurance firms. For many years, Colombia's lack of capacity to discern value and its disorganized response to these spontaneous requests for access to new medical innovations have threatened the sustainability of the health system and some of its most important achievements.

MAIN ACHIEVEMENTS OF THE COLOMBIAN HEALTH SYSTEM

Despite its complex nature, the Colombian health system is recognized in the region and referenced by international peers for its achievements in terms of equality and universal health coverage. For example, the OECD health system report for Colombia indicates that, although the country has high levels of income inequality, access to health care and coverage are fair, and its transition to universal coverage has been quick and successful (OECD, 2015).

Colombia has almost reached universal health coverage, which is in line with the main goal of the health reform adopted by the country in 1993. That year, coverage stood at only about 23.5%, but by 2014, this figure had reached 96.6%, according to MSPS estimates using information from the Quality of Life Survey (ECV).

6 Recent regulations eliminate the CTC step. It is now sufficient for the treating physician to simply request a technology that a) is not part of the benefits plan and b) does not correspond to legally excluded services, e.g., aesthetic or experimental treatments, among others (see Resolution 1328 of 2016).

7 Refer to Giedion et al. (2014) and CRITERIA (2015) for further information on this benefits plan.

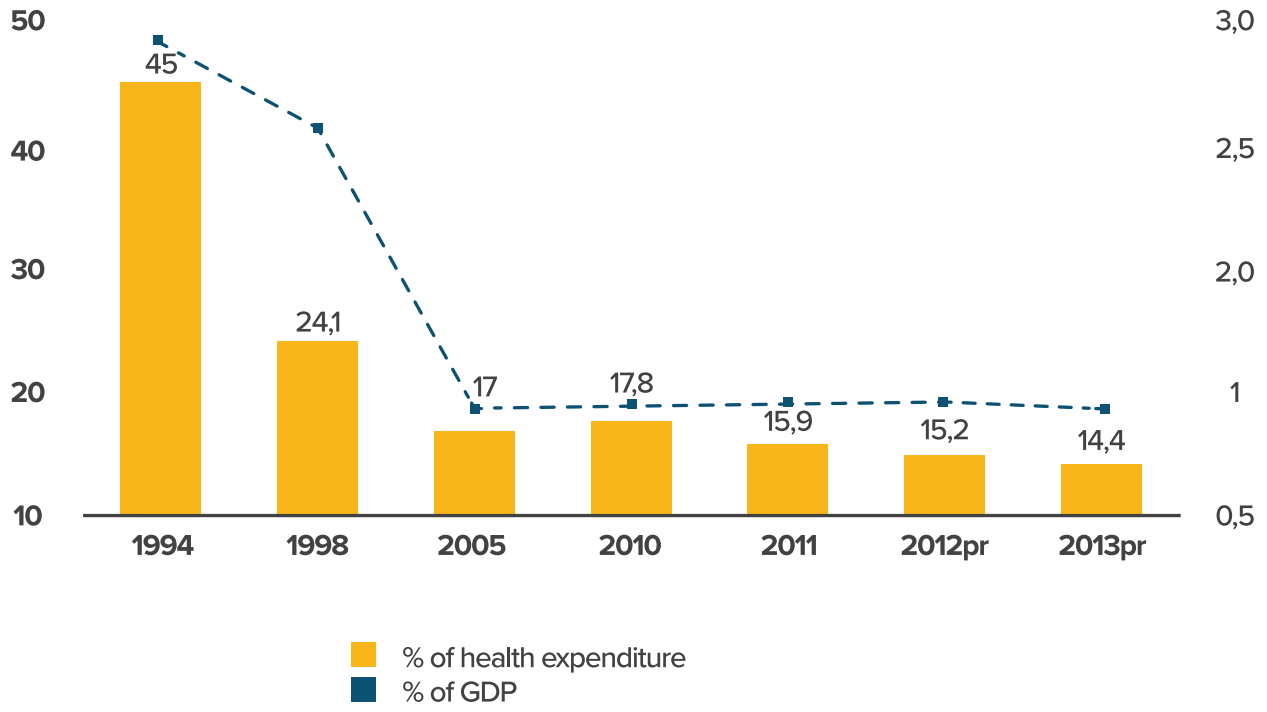
Similarly, before the 1993 reform, the poor had only limited **access** to health insurance coverage, with only about 4% of the population in the poorest quintile enrolled. By 2013, it was estimated that the percentage of enrollees in this quintile rose to 89.8%. Also, coverage in rural areas increased from 7% in 1993 to 91% in 2013. A similar effect was noted in access to health services. In 2003, access to preventive services was about 34% for rural areas and 50% for urban areas, whereas in 2013, the percentages amounted to 50% and 60%, respectively.[8]

One of the areas in which Colombia has shown outstanding results is **financial protection and equality in financing.** This achievement is recognized in the 2010 World Health Report from the World Health Organization, which ranked the country first in terms of fairness of financial contribution. As shown in Graph 1, the structural characteristics of the Colombian health system have allowed for a nearly 30% reduction in out-of-pocket spending as a percentage of total health spending between 1994 and 2013, with out-of-pocket spending representing 14.4% of total health spending in 2013. This percentage is the lowest in Latin America and the Caribbean and well below the average of 30% observed in the region, according to World Bank indicators.

Apart from evidencing the level of financial protection provided by the health system, Graph 1 reveals an interesting fact: in a context of strong technological pressure, almost all technologies are paid for with public funds, while the financial burden assumed by the beneficiary is minimal. This shows a low capacity for discernment by the sector and other agents. The social agreement concerning the kind of technologies to be paid for with public resources and under what conditions is still weak, so as not to say nonexistent, and it is assumed that all technologies can and should be funded by the government. As a result, we have a graph that summarizes two stories: a successful social reform that achieved equality and financial protection, and a society struggling to incorporate health technologies—in a haphazard manner, without priority setting—when resources are, by definition, limited.

8 MSPS calculation based on data from the ECV for the mentioned years.

Graph 1. Out-of-pocket spending in Colombia, 1994-2013



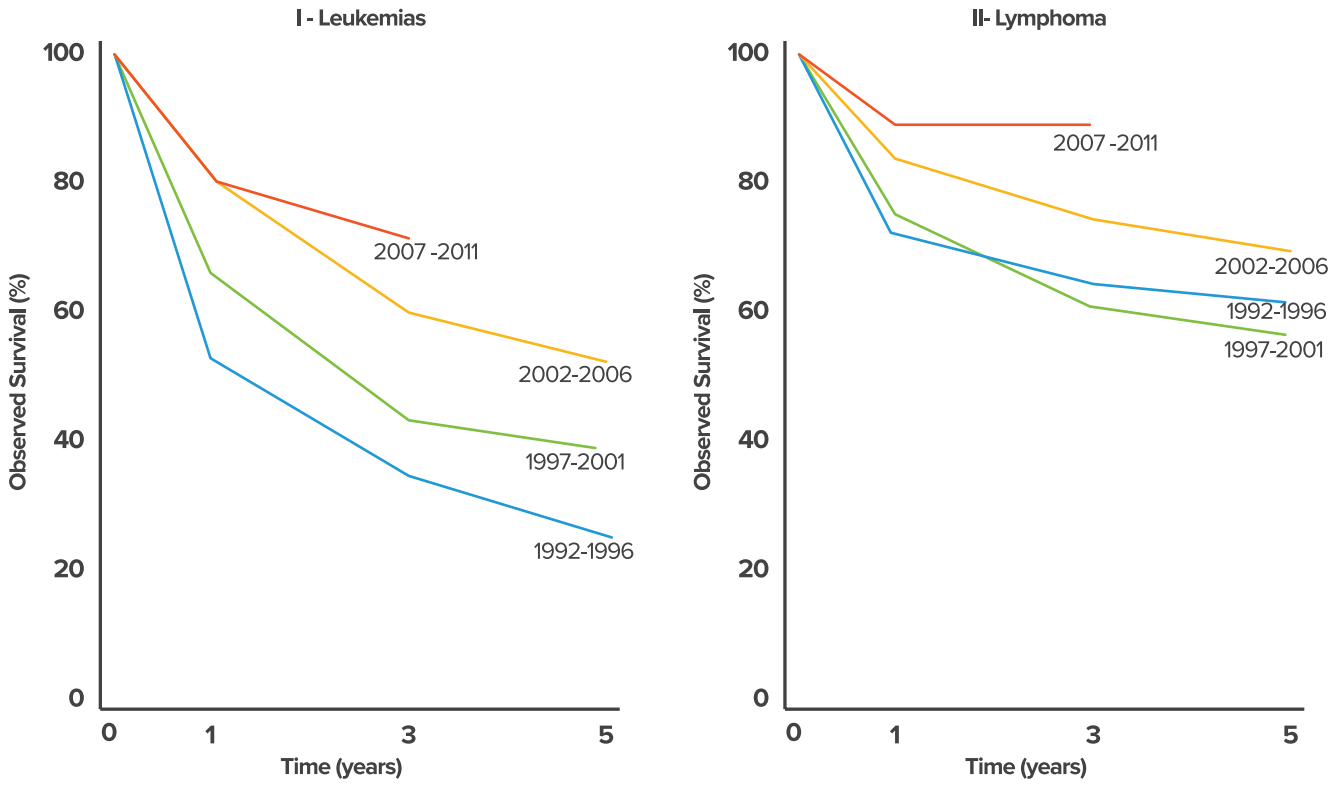
Source: MSPS Calculations. Sectoral Financing Directorate, Health Accounts; DANE and DNP

It is worth asking if past achievements have also resulted in an improvement of the health of Colombians. The answer seems to be affirmative, as shown, for example, by the analysis of the survival rate of children with cancer. For example, in the city of Cali, the survival rate before the reform was about 25% for leukemia and only about 65% for lymphoma (see Graph 2). Almost 20 years later, the system achieved survival rates of almost 70% and 90%, respectively (Bravo, García, Collazos, Aristizabal, & Ramírez, 2013).

Other indicators reflect the achievements of the system in terms of Colombians' health status. Life expectancy has increased to around 72.1 years for men and 78.5 years for women. Infant mortality rates have also declined substantially. In 1970, they were at about 40 per 1,000 live births, and in 2013, figures were 12.8 per 1,000 live births, according to the MSPS.

While the causal factor is difficult to prove, these achievements are due, at least in part, to insurance coverage and access to essential medicines that the entire population is entitled to through the POS. These achievements are potentially threatened by the haphazard incorporation of the latest technologies in health and the accompanying sustainability issues.

Graph 2. Childhood cancer survival rates in Cali, Colombia



Source: Bravo, Luis Eduardo, et al., Descriptive Epidemiology of Childhood Cancer in Cali, Colombia 1977-2011.

TECHNOLOGICAL PRESSURE THROUGH A PARALLEL BENEFITS PLAN: NON-POS TECHNOLOGIES

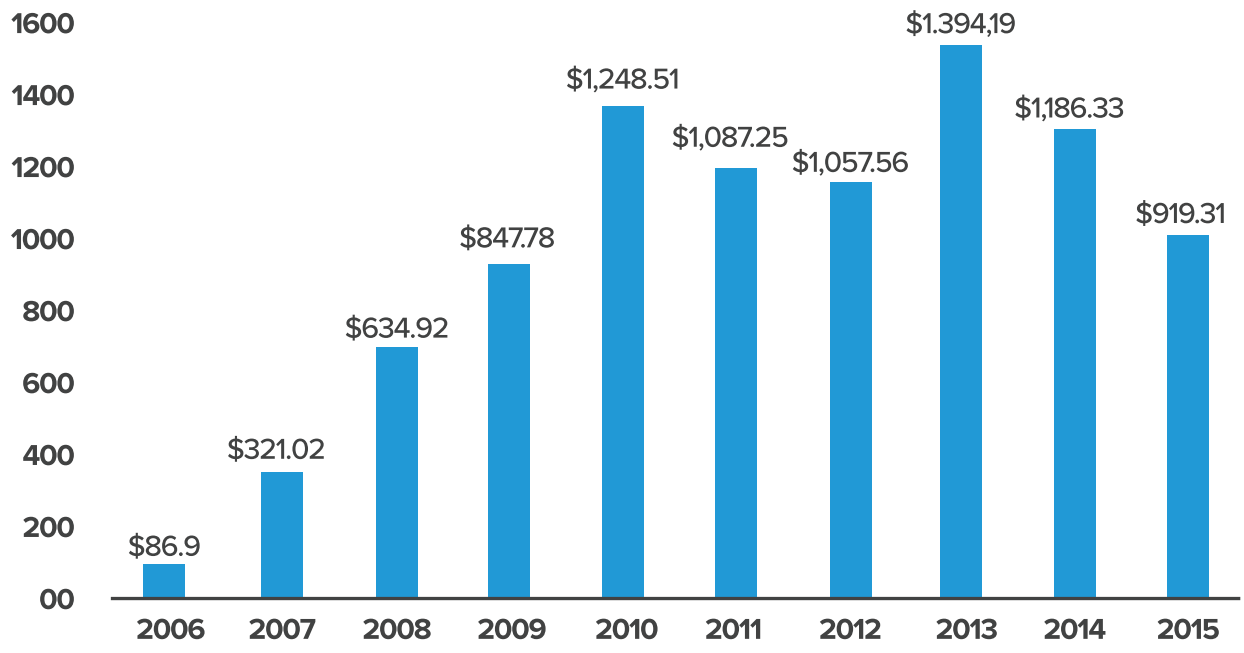
The possibility to access technologies excluded from the POS through writs of protection or CTCs has given rise to what could be called a **parallel benefits plan**, commonly referred to as **non-POS technologies.** This parallel benefits plan has evolved spontaneously, and it encompasses all of the technologies that are not explicitly included in the POS.

The haphazard adoption of non-POS health technologies in Colombia is mainly due to regulatory gaps that allow access to any type of technology through writs of protection and CTCs. This situation created incentives for various stakeholders interested in granting access to different health technologies: insurers, doctors and specialists, patient associations, providers, and judges, among others. Prescribing a technology excluded from the POS generates a series of economic gains in terms of price and quantity, especially for the pharmaceutical industry.

As shown in Graph 3, the most important growth in the funding of non-POS services occurred between 2005 and 2010. During the health insurance system's maturation period and the related surge in the use of health services, the amount of public resources allocated to fund non-POS services increased almost tenfold. The share of non-POS reimbursements as a percentage of the contributory scheme jumped from 0.9% in 2003 to 18.5% in 2010 (Nuñez, Zapata, Castañeda, Fonseca, & Ramírez, n.d.).

Initially, non-POS services were paid for with the savings that the system accumulated during its early years; however, by 2009, the depletion of the former surplus and rising health claims made it increasingly challenging to pay for these non-POS services.

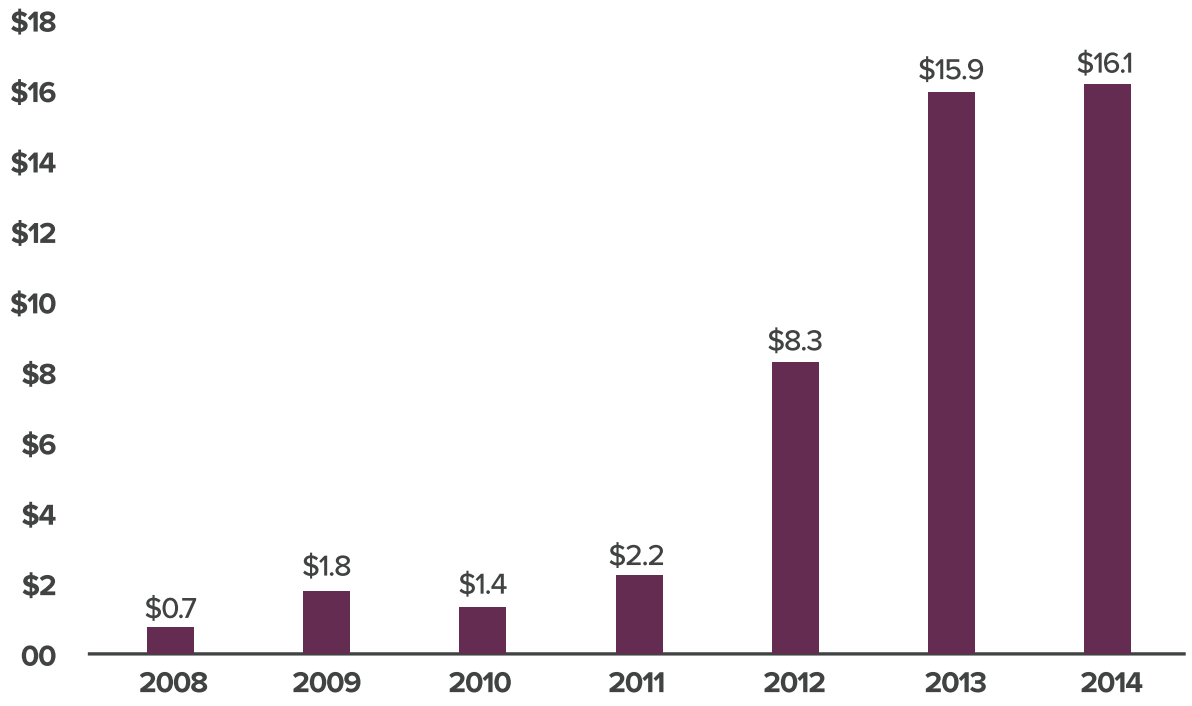
Graph 3. Non-POS value reimbursed with public funds (in millions of dollars)



Source: FOSYGA - MSPS calculations (This information contains all values approved by all presentation lines.)

One example of a medication that was not included in the POS, yet captured a significant and increasing amount of public resources through writs of protection and CTCs, is presented in Graph 4. Reimbursements for Soliris (eculizumab), one of the most expensive medications in the world,[9] totaled less than US$1 million in 2008, but only six years later, total reimbursements had skyrocketed to more than US$16 million. The Colombian health system paid US$16.2 million—the price set by the pharmaceutical industry—out of public funds for a non-POS medication that benefited only 65 patients.

Graph 4. Value reimbursed for Soliris (eculizumab) (in millions of dollars)



Source: MSPS

9 http://www.forbes.com/2010/02/19/expensive-drugs-cost-business-healthcare-rare-diseases.html

The government sends a clear signal to the market when it publicly finances technologies without any sort of filter, discernment or organized decision-making with regard to these kinds of high-cost medications that are not included in the benefits package. Pharmaceutical companies take notice of the availability of resources and feel encouraged to further increase their market share. As anecdotal evidence, consider the 2010 edition of a pharmaceutical trade publication that pointed to Colombia as the most attractive place for the industry to sell innovative technologies.

The non-POS track enabled not only the abrupt entry of new health technologies but also the reimbursement of technologies at whatever price the market dictated, since their value failed to correspond to any technical criteria. This trend was especially evident among **medications,** which represent the largest share of non-POS reimbursements; they make up 81% of the total number of non-POS reimbursements, and they account for 75% of the total value of all non-POS technologies reimbursed with public funding (Franco, 2015). The country's lack of price regulation for medications encouraged pharmaceutical companies to sell their medications in Colombia at much higher prices than those observed in other countries, with no clear therapeutic justification.

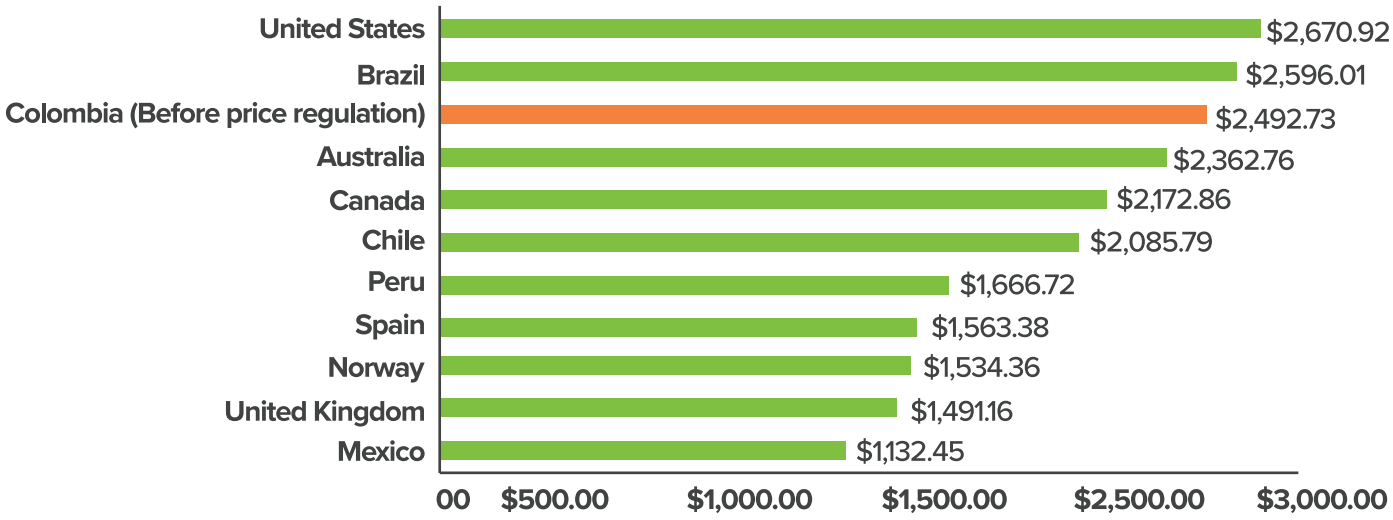
An example of this practice can be seen in Graph 5, which compares the price of MabThera (rituximab), a drug used to treat non-Hodgkin's lymphoma or rheumatoid arthritis, among several countries. According to this comparison, out of 10 markets observed, Colombia has the third most expensive price, just behind Brazil and the United States, and its cost is just less than double the price recorded in Mexico.[10]

These comparatively high prices were initially noted in nearly 860 medications. Some of these price comparisons can be observed in the "medication pricing thermometer" created by the MSPS to illustrate the important price differences that existed before the government adopted a policy of price regulation, as described below.

As previously discussed, two events triggered the explosion of public spending for services not included in the benefits package: the sudden entry and use of high-cost technologies and higher prices compared to those of other countries.

10 This information may be found at https://www.minsalud.gov.co/salud/MT/Paginas/herramienta-interactiva-de-consulta-de-precios-regulados-de-medicamentos.aspx.

Graph 5: Rituximab price, one 50-mL vial (in dollars)



Source: Regulated medication pricing thermometer, MSPS

SOME CONSEQUENCES OF THE GOVERNMENT'S WEAK CAPACITY FOR DISCERNMENT

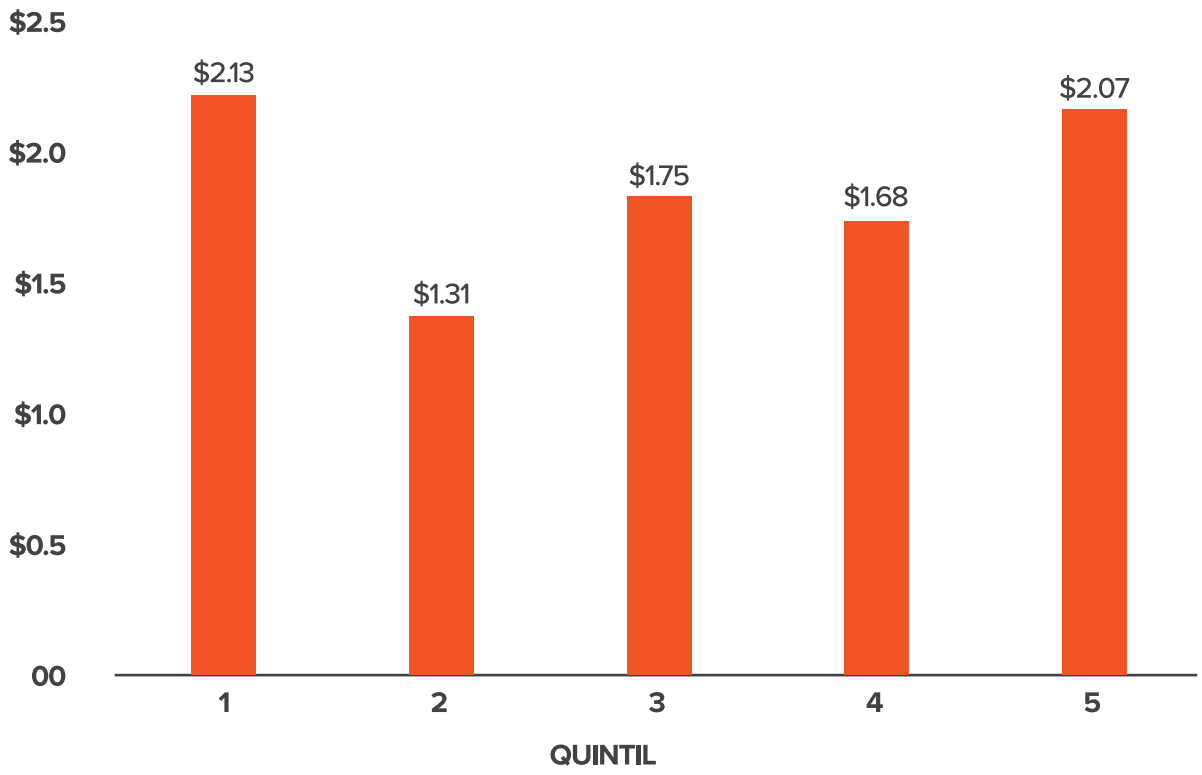
The inclusion of technologies without the capacity of the government to discern value threatens **the financial sustainability** of the system. One of its consequences **is the gradual financial collapse of agents through a domino effect.**

This effect can be understood by an explanation of the flow of resources entailed by a non-POS request. Once the request is approved, the insurer is required to guarantee the service and to front the cost. Then, the insurer seeks reimbursement from the government, which, in turn, evaluates the insurer's request and decides whether to pay based on certain parameters. If the government denies the reimbursement, the request is returned unpaid, and the insurer ends up bearing the cost of the service. This situation leads to a delay in payment by the EPSs for health services. As a result, many EPSs have unpaid debts with health services providers, causing financial problems at the service delivery level and creating a **domino effect** that has disturbed the financial equilibrium of key health system stakeholders.

The unrestrained growth of non-POS technologies has also led to negative consequences for the financial **equity of the health system**. Studies have indicated that services excluded from the benefits plan are claimed equally by people in quintiles 1 and 5 (Franco, 2015). Graph 6 shows that the per capita value of a non-POS claim is very similar

for the first and fifth quintile. This situation is inequitable, as non-POS technologies are being granted equally to all claimants, irrespective of each person's purchasing power and ability to pay. Should the goods and services excluded from the POS be equally granted to all? Or, on the contrary, should the purchasing power of claimants be considered as a criterion when deciding to publicly finance the requested services? The aforementioned situation poses a potential threat to equity, which is one of the most important achievements of the Colombian health system.

Graph 6. Value of a non-POS claim per person, 2012 (in millions of dollars)



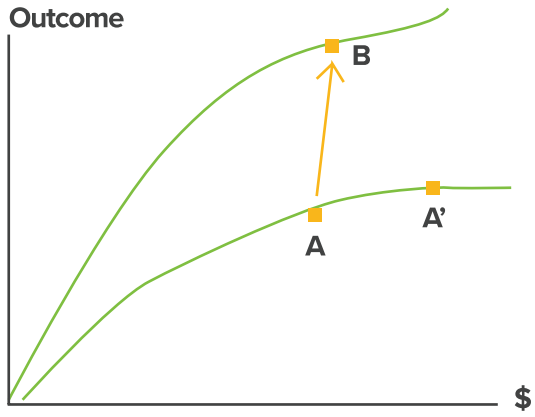
Source: MSPS

POLICY SOLUTIONS TO STRENGTHEN THE CAPACITY FOR DISCERNMENT

The strengthening of governments' capacity to discern the value of health technologies should not be understood as opposition to the public financing of health innovations. Instead, it means that governments should not rush to pay for health technologies at any price, under any circumstance, and that, before anything else; they should undertake a thorough exercise in discernment with regard to the technology's value.

In the search for ways to prevent technological pressure from collapsing the health system, Colombia has started to think about the need to align the prices of medicines with their **therapeutic value**. Graph 7 illustrates this idea. In the first scenario, there is a technology A used to treat a certain pathology. As the result of innovation, two new technologies are introduced to treat this pathology: technology A′ provides a slightly greater benefit but at a higher price, while technology B provides significantly better therapeutic results at a price almost equal to technology A. In recent years, Colombia has been introducing both options A′ and B (through the POS and as non-POS technologies), even though technology B appears to be the natural choice, showing once again the government's limited capacity for discernment.

Graph 7. Innovations, price and value



Source: MSPS

To ensure that technology B is chosen over technology A′, an organized and legitimate institutional mechanism is needed to allow decision makers to socially validate the preference of B over A′. What is being sought in this case is to be able to socially and legally say yes to technology B and to legitimately say no to technology A′ (or to not paying more for A′ than for B).

Colombia has adopted several policies to seek consistent and sustainable access to new technologies, among them the adoption of a strong pharmaceutical policy, including price regulation and the strengthening of institutions related to the adoption and inclusion of new technologies. These policies are described below.

PHARMACEUTICAL POLICY

Colombia's pharmaceutical policy rests on three key elements: drug price regulation, competition through biosimilars, and promotion of transparency in physicians' prescriptions.

Drug price regulation was carried out in two stages. First, the government regulated non-POS drug prices by setting a maximum reimbursement price based on internal price benchmarking. This exercise showed that prices for the same medication had a significant (and unjustified) variation, as reported in Graph 5. Then, regulation was expanded to also cover medications included in the POS, employing an international reference pricing method that takes the public prices of 17 benchmark countries and uses the 25th percentile of those analyzed as an indicator. Priority setting for the drugs to be regulated was guided by two criteria: epidemiological relevance and impact on health spending.

It is worth noting that one of the cornerstones of the country's price regulation policy is transparency. The MSPS publishes its price benchmarking methodology and provides spaces for regulated agents to ask questions.[11] Failure to comply with regulations results in penalties by the Superintendency of Industry and Commerce (SIC),[12] with fines already having been issued several times.[13]

Price regulation has been accepted by the regulated parties and by most other stakeholders but, most importantly, by society in general. Thanks to the ministry's efforts, Colombia has seen a price reduction in 863 regulated medications (with reductions ranging from 30% to 90% in 2013), for a savings of about US$183 million. For example, the price of the previously mentioned medication rituximab fell from an initial price of US$2,492 to US$1,600, equivalent to a 35% decrease.

Finally, it is worth mentioning that the government is working to prevent the market from compensating for price reductions in other ways (i.e., through other sales channels). Likewise, strategies are being designed to establish the price of a drug as soon as it enters the Colombian market (i.e., when the pharmaceutical company receives authorization to market its drug in the country) to deter the sudden introduction of new high-priced drugs before they can be evaluated. This regulation seeks to ensure that cost-effectiveness serves as a criterion when setting the highest price at which a drug can circulate in the market. This policy will be further discussed in the following section.

11 https://www.minsalud.gov.co/salud/MT/Paginas/medicamentos-regulacion-precios.aspx

12 The SIC is a Colombian regulatory agency in charge of regulating fair business practices and promoting competitiveness. It also acts as Colombia's patent and registration office.

13 http://www.elheraldo.co/nacional/sic-sanciona-6-laboratorios-por-supuestos-sobrecostos-de-medicamentos-226398

Legislation that allows for **biosimilar competition** in the country is the second key policy measure that has been adopted. This regulation, implemented through Decree 1782 of 2014, stipulates three tracks to request marketing authorization for biosimilars in Colombia: two tracks developed by other countries, plus a fast track for well-characterized molecules, which does not require recent phase II and phase III clinical trials to grant marketing authorization. The purpose behind the decree is to eliminate unnecessary barriers to access in order to encourage competition, which is expected to reduce the prices of these medications.

The decree was the focus of serious discussion among system stakeholders before and after being publicly presented, and the policy is now considered a benchmark not only for countries in the region but for the world. This policy also consolidated the message that the Colombian government wanted to send to the pharmaceutical industry: Colombia was not willing to pay just any price for just any health technology.

Another element that is currently being strengthened is the policy for **transparency and self-regulation of health professionals.** Colombia is planning to adopt its own version of the Sunshine Act,[14] together with an initiative for the rational use of medications.

INSTITUTIONAL STRENGTHENING

In order to achieve the rational incorporation of health technologies, Colombia sought to strengthen its health institutions through the **creation of the Health Technologies Assessment Institute (IETS),** which aims to provide evidence-based information and tools that allow the ministry and other health authorities to make informed decisions about health technologies.

The IETS has been functioning for about three years, and after approximately 120 evaluations, it has gained recognition in the sector. This recognition has lent increased legitimacy to its decisions to incorporate technologies, and it has also improved communication with the ministry and the health authority.

Along the same lines, Colombia has worked to **strengthen the institutional framework related to the market entry of new health**

14 The Physician Payment Sunshine Act is a 2010 United States health care law that aims to increase the transparency of financial relationships between health care providers and pharmaceutical manufacturers. It requires the manufacturers of drugs, medical devices, biological and medical supplies covered by the three federal health care programs—Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP)—to collect and track all financial relationships with physicians and teaching hospitals and to report these data to the Centers for Medicare and Medicaid Services (CMS). (Wikipedia).

technologies[15] by coordinating the actions of the technology evaluator (IETS), the regulatory agency,[16] and the entity responsible for the regulation of health technology prices. This effort is meant to ensure that, during the process of granting a marketing authorization, the technology's price is established on the basis of the comparative therapeutic value determined through the health technology assessment. Based on this price, the party interested in marketing a new technology decides whether to introduce the technology to the market. This policy seeks to ensure that A′ medications do not enter the health system with a higher cost than B medications; instead, their price must be established in accordance with their therapeutic value (close to A).

Finally, it is important to mention that the country is about to face a major challenge: the definition of a **new benefit plan based on exclusions.** This process will require making decisions on those technologies that will **not** be covered, which currently include aesthetic/cosmetic technologies, experimental technologies, technologies provided abroad, or technologies without any solid evidence of therapeutic benefit. Apart from posing a technical challenge, defining a new benefit plan represents a social challenge in that it must establish a consistent agreement with beneficiaries and other agents of the system. Consistency of the **social contract requires the following: consistency between the benefit and available resources, awareness of a dual responsibility (to not only the beneficiary but also the system), and alignment of incentives.**

15 Article 72 of Colombia's National Development Plan is an intersectoral law that outlines and approves the government objectives for all sectors every four years. The National Medication and Medical Device Price Commission is responsible for price regulation, as per Resolution 1438 of 2011.

16 The National Institute of Food and Drug Monitoring (INVIMA) is the institution responsible for granting marketing authorizations, known as sanitary registries in Colombia.

CONCLUSION

The story told through this *Breve* shows that the achievements of the Colombian health reform—inspired by the ideals of equality and solidarity—which have allowed the population to enjoy increasingly equitable access to the health system and substantial financial protection, may be in jeopardy, due to the lack of institutional capacity to react to the pressure of new health technologies.

This leads us to reflect on governments' capacity for discernment, with respect to the incorporation of new health innovations into the system, especially when it is unclear whether they should be publicly funded. Colombia has taken steps to strengthen its ability to discern value, namely: a) it has strengthened its capacity to evaluate health technologies through the creation of the IETS; b) it has improved the alignment and coordination between the regulatory agency, the IETS and health authority; and c) it has implemented a price regulation policy that seeks to use the comparative therapeutic value of health technologies to set prices. Together, these policies provide evidence of the fact that the country is not willing to pay just any price for just any health technology.

REFERENCES

Bravo, L. E., García, L. S., Collazos, P., Aristizabal, P., & Ramírez, O. (2013). Descriptive epidemiology of childhood cancer in Cali. *Colombia Médica* , V 4.Obtained from Descriptive epidemiology of childhood cancer in Cali.

CRITERIA. (2015). *The Colombian Benefits Plan, what does it leave us with? Based on a webinar with Claudia Vaca Obtained from Red Criteria:* https://publications.iadb.org/handle/11319/7293

Ombudsman's Office. *Obtained from LA TUTELA Y LOS DERECHOS A LA SALUD Y A LA SEGURIDAD SOCIAL 2014:* http://www.defensoria.gov.co/public/pdf/LatutelaylosderechosalaSalud.pdf

Franco, C. (2015). Recobros: *Who benefits and who doesn't?* Obtained from Universidad Nacional de Colombia: http://www.bdigital.unal.edu.co/51786/1/1032448529.2015.pdf

Giedion, U., & Cañon, O. (2014). Colombia: the Compulsory Health Plan, . In U. Giedion, & R. Bitran, *in Health Benefit Plans in Latin America: a regional comparison* (pp. 81-113). Washington DC: Inter-American Development Bank.

Ministry of Health and Social Protection (12 of 2013). *Ministry of Health and Social Protection Obtained from Health Sector Financial Figures:* https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VP/FS/Boletin%20Cifras%20finacieras%20del%20Sector.pdf

Nuñez, J., Zapata, J., Castañeda, C., Fonseca, M., & Ramírez, J. FINANCIAL SUSTAINABILITY OF THE COLOMBIAN HEALTH SYSTEM.

OCDE. (DEC of 2015). OCDE. Obtained from OECD *Reviews of Health Systems: Colombia 2016:* http://www.keepeek.com/Digital-Asset-Management/oecd/social-issues-migration-health/oecd-reviews-of-health-systems-colombia-2015_9789264248908-en#page3

World Health Organization. (2000). World Health Report. WHO.

Yamin, A. & Parra-Vera, O. (2009). *How Do Courts Set Health Policy? The Case of the Colombian Constitutional Court. Published online 2009 Feb 17. doi:* 10.1371/journal.pmed.1000032 PMCID: PMC2642877. Obtained from NCBI: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2642877

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