LOCAL MALADIES, GLOBAL REMEDIES:

RETHINKING RIGHT TO HEALTH DUTIES

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1. Introduction

In this paper we will argue that the current global arrangement that defines access to life-saving pharmaceuticals should be contested and reformed. This current global arrangement privileges price-setting as the only mechanism to reward Research and Development (R&D) investments by Big Pharma companies. More concretely, we will stress that the current global arrangement divests Big Pharma companies from any duty burden before local right-holders (individuals that demand access to live-saving pharmaceuticals) and local duty-bearers (governments that try to deliver pharmaceuticals to their vulnerable population). We will argue that the Colombian case exemplifies the negative effects of the extant global arrangement, where global right holders' interests (Big Pharma's IPRs) trump over local right-holders and duty-bearers. Moreover, we will show how litigation on exclusive,[1] expensive medication has brought about disproportionate benefits to transnational IP right-holders at the expense of local duty-bearers. We will also depict how during the last decade thousands of Colombian right-holders used a judicial action for the protection of basic rights --Tutela-- to demand the provision of high-cost pharmaceuticals excluded from the basic health plan (POS),

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[1] By "exclusive" we refer to medication produced by a single company, either because it is protected by Intellectual Property Rights (patents and/or data exclusivity) or because there are no competitors in the global market who own the technology to copy them.

making Colombia the country with the most voluminous and expensive right-to-health litigation in Latin America. We will stress that Colombian law and judicial practice enforced the right to have access to pharmaceuticals by assigning to the government the correlative positive duty to pay for the medications. Hence, a progressive jurisprudence on the right to health allowed thousands of vulnerable and poor individuals to obtain, from taxpayer-financed funds, expensive life-saving medications. We will show that the case of litigation on oncologic pharmaceutical products is a striking example of how the judicial injunction for the protection of basic rights --Tutela-- was instrumental to save thousands of lives of Cancer patients, whose chances of buying extraordinarily expensive pharmaceuticals with their own resources was simply out of the question. Paying for this type of expensive life-saving pharmaceuticals is, in itself, a remarkable achievement for a government of a developing country. Unlike millions of other cases around the developing and developed world, Colombians afflicted by excruciating and highly onerous medical conditions have, in the last resort, a judicial action that may allow them to have access to such expensive, life-saving goods.[2]

However, facing the growth of health-related litigiousness, the Colombian government allowed an across-the-board deregulation of pharmaceutical prices-- which was leveraged by Big Pharma to widen its already considerable pricing discretion. Deregulation of pharmaceutical prices and a comparatively vigorous protection of IPRs in Colombia[3] produced a marked cost-escalation of health-related litigiousness that has

[2] In a comparable case, Perú, where right-to-health litigation is not as extended as in Colombia, more than 50% percent of the population has no other option than paying for oncological medication with out-of-pocket money. This is, in fact, not even an option for many Peruvians, whose net monthly income is far lower than rhe doses of most Cancer bio-tech pharmaceuticals. See AIS (2009).

[3] Unlike other South American countries, with the recent exception of Perú, Colombia committed itself to protect IPRs beyond TRIPS requirements and since 2002 protects new and innovative pharmaceutical

the potential to disrupt the financial stability of the Colombian health sector, affecting thereby millions of individuals. We will suggest that by deregulating pharmaceutical prices the government failed to comply with the *duty to protect* its population's right to health from powerful third parties such as Big Pharma companies.

Nonetheless, we will contend that even if countries comply with the *duty to protect* by regulating pharmaceutical prices --or even by instigating TRIPS flexibilities such as compulsory licensing or parallel imports-- Big Pharma companies, thanks to the global arrangement that benefits them, are still exempted from any duty-compliance before local right-holders and duty bearers. This, ultimately, makes highly unlikely that countries like Colombia, even if taking a more active stance towards price regulation, could comply with the duty to protect by delivering more affordable pharmaceuticals to their vulnerable population. Henry Shue's idea about a global redistribution of the burden of duties for the realization of socioeconomic rights will help us to contest the negative effects of the extant global arrangement, as exemplified by the Colombian case. Shue's idea will also be instrumental to suggest why we need a global mediating institution capable of assigning a burden of duties to Big Pharma companies.

2. Taking Rights Seriously --and the costs of doing it

The extant literature reveals that Colombia is the Latin American country with the highest volume of right-to-health litigation.[4] Colombia is an outlier even when compared

products with 5 years data exclusivity –which means that the data presented to the Sanitary Authority (INVIMA) for commercialization approval are kept confidential during that period.

[4] Costa Rica is a country with an active rights-based litigation. However, there is no trace in the literature of a litigation cascade on the right to health comparable to the Colombian and Brazilian cases. See Wilson (2009), Wilson & Cordero (2006). Argentina, on the other hand, is witnessing a growth in its precedent on the right to health. However, the data compiled by Bergallo on that country shows that the volumes of right-to-health litigation are still low compared to the Colombian and Brazilian cases. See Bergallo (2005).

to Brazil, the other Latin American case with robust right-to-health litigation.[5] For example, a study published by Colombia's Ombudsman's office revealed that in 2004 1 of every 597 Colombian citizens used the basic rights injunction for the protection of basic rights (Tutela) in order to obtain health-related goods and services --most commonly medications, medical procedures, chirurgical interventions, medical appointments, prosthetic devices. Hoffman & Bente's study --whose data on right-to-health litigation in Brazil is by far the most comprehensive and detailed-- shows that in Rio Grande do Sul (the Brazilian state with the highest volume of right-to-health litigation) there is 1 legal health rights action for every 2,848 inhabitants.[6] These figures illustrate that in 2004, even when compared to the Brazilian state that shows the most voluminous right-to-health litigation (Rio Grande do Sul almost doubles Rio de Janeiro, the second most active Brazilian state in terms of right to health litigiousness) Colombians used legal health rights actions almost five times as often. This is all the more striking if one observes (See Table 1) that in 2004-2008, the volume of right-to-health litigation almost doubled in Colombia, reaching a level where right-to-health litigation amounted to 41.5% of the total of basic rights legal actions in Colombia. Taking into account all of the data gathered by the Ombudsman's Office study during the period 1999-2008, 674,612

The data on the remaining Latin American countries suggests that judicial mechanisms for the protection of the right to health are indeed used, but not on a scale comparable to the Brazilian and Colombian cases. See Brewer-Carias (2009).

[5] A study published by *The Lancet* suggests that Colombia is the country with the most voluminous right-to-health litigation --on pharmaceuticals-- in the developing world. However, the results of this study have to be interpreted carefully, since the data collection methodology used in this study – primarily internet-based and with no reference/exposure to actual judicial records-- is highly unreliable. Horgerzeil et. al (2006)

[6] (2004: 117)

citizens (in a country of approximately 43 million inhabitants) used the basic rights injunction Tutela to demand access to health-related goods.[7]

--Table 1--

The economic cost --most of which is assumed by taxpayers-- of the booming right-to-health litigation is a particularly troublesome issue in Colombia. Although the cost-escalation associated with right-to-health litigation is also a growing concern in Brazil,[8] its negative impact on the financial stability of the health sector is still a far cry from that in Colombia.

Colombia's expenditure on pharmaceutical products experienced a sharp increase over the last decade–rising from 1.2% of the GDP in 2001 to 1.3% of the GDP in 2006,

[7] Defensoría del Pueblo, Colombia (2007, 2009).

[8] The overall costs of right-to-health litigation are a matter of growing political and academic discussion in Brazil. Due in large part to the lack of reliable information about right-to-health litigation at the state and municipal level, assessing the real dimensions of its cost has been tricky for Brazilian scholars. See Messeder et. al (2005), Scheffer et. al. (2005), Hoffman & Bentes (2004), Motta (2009). Nonetheless, the fragmentary picture offered by the available partial data, although not entirely comparable with the bleak Colombian case, raises many eyebrows. According to Motta, during 2008 around US$21 million (about 1% of the Federal total health budget) were spent by the Brazilian Federal government in pharmaceuticals ordered by judges. This figure, dwarfed by the Colombian case, becomes more serious if the State-level is considered. In 2004, Sao Paulo (the largest and most populous Brazilian state) spent 10% of its US$ 261 million health budget on pharmaceuticals ordered by judges (Ibid). Moreover, the cost-escalation trend seems to be growing at worrisome rates. In 2008, the money spent at the federal level on buying pharmaceuticals ordered by courts was three times higher than the 2007 expenditure See Motta(2009). Nonetheless, the strategies used by the Brazilian government to curb the cost-escalation of right-to-health litigation differ markedly from those adopted by the Colombian government. In Brazil in 2007, the Ministry of Health created a commission for the Rational Use of Medicines (*Comissão para o Uso Racional de Medicamentos*), given the task of designing basic guidelines for the use of SUS-included medicines. These guidelines are tailored for the use of public officers, judges among them. Moreover, as the study conducted by Schaeffer shows, right-to-health litigation has been used as a "canary in the coal mine" for policy makers. See Schaeffer (2005). That means that "litigation can work as a signaling mechanism for demands in new medicines, and hence, for the expansion of an existing public policy." See Hoffman (2004:137). Since the 90s, antiretroviral-based litigation helped policy makers at the federal and state levels to assess which pharmaceuticals should be regulated and added to the Obligatory Health Plan--SUS. On the other hand, the Brazilian Federal government and the 25 States buy medications through a centralized importation process, whereby Big Pharma companies have to negotiate prices directly with the Federal government or with the state-level authorities.

to 1.43% of the GDP in 2008.[9] As Figure 1 illustrates, only the cost of treatments and medications that are not included in the Basic Health Plan paid to private HMOs by the tax-financed fund FOSYGA escalated from US$ 2.8 million in 2001 to US$ 605.3 million in 2008. The latter figure represents 17% of the total governmental pharmaceutical expenditures and was primarily spent on expensive chemical and biotechnology drugs produced by Big Pharma companies.[10] During 1997-2008, at least half of these pharmaceuticals were demanded by individuals using the basic rights injunction Tutela. Moreover, right to health litigation amounted during the period 1997-2008 to US$ 1.14 billion[11]. Cases of plaintiffs demanding costly imported pharmaceutical products, prosthetics, plastic surgery, overseas treatments, became *causes célèbres* used by critics to chastise the Court's magnanimity. Predictably, many neoliberal-minded economists accused the court of unleashing, through purely deontological, counter-majoritarian and consequence-blind rulings, a financial pandemonium capable of crippling the entire health sector. Although the Court's critics were misguided in placing all the blame of the health sector crisis on the deontological nature of the right to health rulings, the fact was that by 2009, some of their predictions became true: the cost of health litigation climbed from US$ 1.48 million in 2001 up to US$ 344 million in 2008[12] (Figure 1).

--Figure 1--

[9] The rise of pharmaceutical expenditure versus GDP is all the more striking if one considers the fact that according to the Colombian National Department of Statistics (DANE), the average increase of GDP between 2001 and 2008 was 5.7%. The data on pharmaceutical expenditure are derived from Zerda et al.(2001) and Cortés (2009).
[10] See Andia (Andia 2010).
[11] Fosyga's finantial statement, 2008.
[12] Ibid

By 2010, the government depicted a catastrophic scenario and argued that the taxpayer-financed fund FOSYGA used to reimburse HMOs for their services was running dry. The financial collapse was closely associated with the cost-escalation of right-to-health litigation; an overall paralysis of the Colombian health sector seemed, according to the Colombian government, just a stones-throw away. Facing this financial meltdown, in January 2010 the Colombian government --using extraordinary provisions entrenched in the Constitution-- declared an economic state of emergency in order to issue a series of controversial decrees that, among other things, curtailed the right to health of Colombians and practically rendered the Tutela useless as a means of obtaining medications and procedures denied by HMOs. Following an uproar from public opinion and massive patient and doctor demonstrations, the Constitutional Court decided that most of the decrees were unconstitutional --only the tax measures that funnel more resources to the health sector were upheld by the Court.

3. New Constitutionalism, Health-Sector Reform and Deregulation: Nurturing a Perfect Storm

In the 1991 Constitution the entrenchment of a judicial mechanism for the protection of basic rights and the creation by the Colombian Constitutional Court of a justiciable right to health provided many citizens with effective means to demand access to health-related goods such as high-cost pharmaceuticals. Thousands of judicial rulings compelled HMOs to provide high-cost medication to patients who argued that the provision of a specific pharmaceutical, despite being excluded from the basic health plan, was instrumental for their subsistence. Nonetheless, the basic legal rules of the Colombian health system

compelled the taxpayer-financed fund (FOSYGA) to reimburse HMOs for the costly pharmaceuticals that they had to provide following a judicial ruling. HMOs argued -- correctly, at least in legal terms-- that based on the extant legislation they did not have the duty to provide expensive pharmaceuticals and treatments excluded from Colombia's basic health plan. The government's reimbursements to HMOs, nonetheless, occurred in a heavily deregulated health sector, where prices of high-cost pharmaceuticals reached heights unknown in other countries of the region. This fact, ultimately, explains the spiraling of costs associated with right-to-health litigation. In this chapter we show how deregulation of pharmaceutical prices blended, in an unpredicted and damaging way, two of the most overarching transformation in Colombia during the last two decades: the rights revolution spearheaded by the Constitutional Court since 1992 and the 1993 reform of the health sector. We would also argue that, unlike Colombian taxpayers, Big Pharma companies are net winners in the cost-spiraling of right-to-health litigation in Colombia.

3.1. **New Constitutionalism and Colombia's rights revolution**

In explaining the explosion of health-related litigation in Colombia the first point to be made is that in 1991 that country adopted a new form of political organization based on the basic precept of New Constitutionalism,[13] that is --according to Stone-Sweet-- "the precept that rights and effective rights protection are basic to the democratic legitimacy of the state."[14] The transplant to Colombia of this new precept occurred under the aegis of the new 1991 Constitution and was spearheaded by the Constitutional Court and by the

[13] For a general overview of the literature on new constitutionalism, see Ackerman (1997), Ginsburg (2003), Hirschl (2004), Arango (2003).
[14] (2008:72).

massive use of the judicial mechanism for the protection of basic rights, known in Colombia as *Tutela*.[15]

In a 1992 ruling, following the hallmark of the right to "Existential means" decisions (Existensminimum) pioneered by the German Constitutional Tribunal, the Constitutional Court created a justiciable right to health by underlying its close association with human subsistence.[16] The fact that the fundamentality of biological subsistence[17] is less disputed among plural conceptions of the good life than an appeal to human dignity, freedom or equality,[18] made subsistence an especially solid cornerstone for the nascent basic right to health. In its 1992 ruling the Constitutional Court concluded that by virtue of being what Frank I. Michelman called a "constitutional right to the means of subsistence,"[19] health ought to be considered a justiciable right despite its exclusion from the list of basic rights entrenched in the 1991 Constitution.[20] Additionally,

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[15] According to Stacy, "The 1991 Colombian Constitution replaced the 1886 Constitution, which contained few fundamental rights. The new Constitution encompasses a broad range of negative and positive provisions, including economic, cultural, and collective rights, as well as civil and political rights…. And also provides two important new judicial mechanisms for the protection of rights and liberties –a separate Constitutional Court and the tutela. The tutela is a citizen injunction that allows any person to seek immediate judicial protection when their Constitutional Rights are violated or threatened by either the government or a private person. All tutelas are forwarded to the Constitutional Court for discretionary review". See Stacy (2009:128)

[16] Decision No. T-484/92 of August 11, 1992. Brewer-Carias summarizes this decision as follows: "The plaintiff in the case, also infected with HIV/AIDS, claimed that he was infected while covered by the Social Security Program... the Constitutional Court, when reviewing the case affirmed that health is a right that 'seeks the assurance of the fundamental right to life'". See Brewer-Carias (2009: 250)

[17] Perhaps the most influential definition of basic rights based on an appeal to human subsistence is Henry Shue's. In a 1996 book Shue defined basic rights as those "essential to the enjoyment of all other rights." Socioeconomic rights that protect subsistence and fundamental human needs are basic because they level the playing field for the rest of rights. According to Shue's rationale, socioeconomic rights to have access to a minimal core of material essentials such as nutrients, water, life-saving medication and medical treatment are as basic as civil/political rights and should be enforced accordingly. See Henry Shue (1996:19)

[18]Nonetheless, there is a price tag attached when choosing a subsistence-based account for basic rights. Katharine Young attacks Shue's approach to basic rights for its failure to connect subsistence with values such as dignity. Young argues that "Most significant is the objection that the minimalist focus on survival and life misses the important connections between dignity and human flourishing that are intrinsic to many interpretations of the right to life." See Young (2008:8).

[19] (1979:659).

[20] This antiformalist constitutional interpretation performed by the Court was heavily criticized by part of the pre-1991 Colombian legal elite -- representatives of a textualist, statute-based, and formalist

a more expansive appeal to a dignified and flourishing human life helped to bolster the basic right to health in Colombia.[21] With its 1992 ruling, the recently-created Constitutional Court flexed its muscles for the first time and foreshadowed the scope of the new legal device for the protection of basic rights, the Tutela. Based on this precedent, bio technological medication, dialysis, chemotherapy, antiretrovirals, among many other pharmaceutical products and treatments, began to be massively demanded by hundreds of thousands of citizens whose initial petitions were rejected by HMOs, which customarily argue that they are not responsible for the provision of medication and treatments excluded from the basic health plan.

3.2. Health Sector Privatization as a Social Experiment

On the other hand, during the 1990s Colombia and many other developing countries adopted features of the model of *managed care* --i.e. health care services provided under the administrative control of large, private corporations.[22] Although Chile and Colombia's reforms are considered to be the most radical adoptions in Latin America of the model of managed care promoted by the World Bank and the Interamerican Development Bank, they can hardly be considered as outliers. On the contrary, the reforms in both Chile and Colombia share basic defining features with many structural redesigns of national health

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hermeutical tradition-- and by defenders of "thin" or minimalist approaches to basic rights. As in the case of the U.S., "justificatory minimalism", understood as an approach to human rights that limits the list of basic human rights to those that protect bodily security against suffering and cruelty, is still influential in Colombia. However, since 1991 it had to face the highly elaborate and increasingly orthodox antiformalist interpretations of the bill of rights performed by the Court. For an overview and critique of "justificatory minimalist" approaches to human rights concerned with bodily security as the only justificatory baseline for basic human rights, see Cohen (2004).

[21] Decision T-484/92 ruled that the right to health ought to be protected "whenever such protection is necessary to preserve threatened fundamental rights, such as the right to life and personal integrity (concerning diagnose services, medicines, treatment, surgeries, etc.), or the right to human dignity". See Cepeda (2004:529).

[22] See Groote & Unger (2005), Homedes & Ugalde (2002).

systems carried out by developing countries during the 1990s under the steerage of International Financial Institutions (IFIs) such as the World Bank, the IMF and the Interamerican Development Bank (IDB). In the wake of this global trend, the publication of the World Bank's 1993 annual World Development Report (*Investing in Health*) marked a watershed event since it encapsulated the tenets of a new and highly influential understanding of what developing countries' health systems should do and how they were supposed to be designed. According to the World Bank's document, low or middle-income countries' governments should advance towards more efficient and equitable health systems by creating private or social insurance schemes and by fostering competition in the delivery of health services.[23] Not a single Latin American country was completely impervious to this new understanding of how health systems should be redesigned. Stocker et. al found that the World Bank's model of managed care had been transplanted, to a greater or lesser degree, by all Latin American countries during the 1990s.[24] Even Brazil, despite its commitment to universal health coverage and to a strong public option, implemented reforms that allowed the private sector to gain more participation in the provision of health services.[25]

Yet, despite the similarities with other health reforms in the developing world, the 1993 health system reform implemented in Colombia was a sweeping "social experiment" whose consequences were underestimated by the reformers. Designed by leading economists and technocrats that were part of the "reformist" network built at a global level by IFIs during the 90s, the Ley 100 (the health sector law that encapsulated the reform) was considered at the time a sophisticated public policy that, combining

[23] See Abbasi (1999).
[24] (1999).
[25] See Armada & Muntaner (2001).

equity with efficiency, had the potential to overcome the paradoxes that plagued, since its inception, the inefficient and unfair Colombian health sector. According to a study published by the Panamerican Health Organization,[26] the 1993 reformers, instilled by state of the art tools of technocratic policymaking garnered by IFIs, displaced the former health sector elite, more prone to an epidemiologic and public health approach to policy. As Norman Daniels argues, during the 80s and 90s developing countries implemented health sector reforms "initiated by external agents, such as the IMF and the World Bank, that offer loans only if certain measures are used." That was, precisely, the case of Colombia, where local reformers lacked enough information to assess some overarching and long-lasting effects of the new policy. They operated, as Daniels suggests, under the model of "social experimentation", that is, of trial and error. This is, of course, a thorny path to take if public health is involved. Almost twenty years after, there is an ongoing debate about not only the extent of "error" of the reform, but about the fundamental underpinnings of the 1993 health system overhaul --for instance, whether to implement a Public Health Insurance Scheme is a good idea. Supporters of the reform highlight that since 1993 the insured increased considerably thanks to the solidarity scheme of the model (all of the insured working population contribute to the solidarity fund with 12.5% of their salary, whereas the most vulnerable individuals are completely subsidized). Conversely, critics argue that despite the growth of the insured, the reform brought about a deterioration of social determinants of health[27] such as vaccinations rates, maternal and child mortality and vector-transmitted diseases. Additionally, critics argue that, by privileging coverage, the implementation of the reform underplayed infrastructure

[26] Paho (2002).
[27] See Daniels et. al. (2000).

investment and quality standards in the delivery of health services.[28] For the purposes of this paper, we will highlight that the across-the-board deregulation of the health sector stands out as a major shortcoming of the 1993 reform, rendering unmanageable the *managed care* model trumpeted by IFIs during the 90s.

3.3. **Deregulation as Unmanaged Care**

Some of the new private actors leveraged by Colombia's 1993 health reform—Private HMOs— along with other powerful players–Big Pharma and local pharmaceutical companies—were able to hijack health-sector regulation on behalf of their interests. More concretely, they succeeded in influencing the Colombian government in dismantling a considerable part of the regulatory framework that was supposed to keep their profit-driven interests under check.

As a matter of fact, in 1998 the National Pharmaceutical Price Commission (NPPC) established three regulatory regimes regarding pharmaceutical prices,[29] the strictest of which was intended to control the prices of pharmaceuticals that were produced by less than three different suppliers, and that were, therefore, considered to be 'exclusive' or monopolistic. Cancer products were among the regulated pharmaceuticals. However, in 2004 cancer drugs were pulled out from the regulatory regime, and in 2006 a reform of the entire pricing regulatory system was proposed in order to "respond better to the challenges posed by bilateral trade agreements negotiations."[30] The reform was based

[28] Yepes et. al (2010).
[29] (1) 'liberty'—when there is enough market competition and prices are unregulated but under watch; (2) 'observed and regulated liberty'–when a top reference price is established; and (3) 'control'-when products are exclusive. These regimes already existed for all manufactured products by Law 81 of 1988. The NPPC only specified the 'control' regime characteristics in the case of pharmaceuticals.
[30] This textual reference is taken from the call for proposals, published the Ministries of Health and Commerce, for the study that would shape the new price control regime in Colombia and that was assigned

on a technical study presented by the Ministries of Health and Commerce. Strikingly enough, the study was financed by the local and the transnational pharmaceutical industry.

The new regulatory regime replaced the automatic price 'control' system with a much softer new 'control' regime that applied only to pharmaceutical products for which no competition existed in their therapeutic class.[31] This single change made most of the pharmaceutical market immune to price control, since very few pharmaceutical products have no competitors within their therapeutic class.[32]

The brisk wave of deregulation that followed ran counter, however, to the basic hallmark of the managed care model introduced in Colombia in 1993. The economists who inspired the 1993 health reform argued that strong and effective regulatory agencies were needed in order to control the private actors (HMOs and Big Pharma companies among them) that were supposed to deliver competitive and accessible health-services and products.[33] In the blueprint of the reform a regulatory agency with extended powers to regulate pharmaceutical prices (NPPC) was deemed as an indispensable institution to achieve the goals of the reform. Yet, the NPPC was never fully effective. This fact, added to the 2006 price regulation health system overhaul, made Colombia's pharmaceutical sector a highly deregulated one, where none of the exclusive high-cost chemical and biotechnology drugs are sold under price 'control.'

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to a private economic consultancy firm (Econometría) as soon as the free trade agreement negotiations between the US and Colombia finished in 2006.

[31] This means that even if a specific cancer pharmaceutical product has no more than one supplier, if there are other cancer products available, it is enough to avoid control.

[32] See Andia (2010).

[33] See Londoño & Frenk (1997).

4. The Storm Unleashed

By allowing an across-the-board deregulation of pharmaceutical prices the government staged an artificial paradise for Big Pharma companies. Indeed, Colombia is a country with some of the most expensive pharmaceuticals in the region. Two World Health Organization (WHO) and Health Action International (HAI) studies confirm this fact. The first study compared Colombia's essential medicine prices with those of Bolivia, Perú, Ecuador, Venezuela and Nicaragua, and concluded that Colombia has the highest prices of brand name pharmaceuticals in the Region.[34] The second study, an international price "snapshot" of Ciprofloxacin (a commonly used off-patent antibiotic) in 93 countries concluded that "Colombia showed the largest brand premium, with the originator brand priced at 60 times the lowest priced generic. Colombia also had the highest treatment cost for originator brand ciprofloxacin in the private sector."[35]

This overpricing of pharmaceuticals due to deregulation proved to be toxic when the wave of health-related litigation forced the government to use taxpayer money to pay for high-cost exclusive pharmaceuticals produced by Big Pharma companies. As Table 2 shows, in 2008 the cost of the Top Ten Bestseller high-cost pharmaceuticals in Colombia –many of which were obtained by patients through health-litigation and were paid by the tax-financed fund Fosyga—reached US$ 210 million. Moreover, nine of these ten

[34] See Meza Cornejo et. al (2008).
[35] See the HAI Global Press Release at http://www.haiweb.org/medicineprices/05012010/PressRelease.pdf.

products are sold in Colombia at prices that are between 200% and 540% higher than the ones paid in Argentina, Brasil, Chile, Ecuador, México, Panamá, Perú and Venezuela[36].

--Table 2--

Additionally, as is also shown in Table 2, seven of the ten bestsellers pharmaceuticals are exclusive (Excl.), which means that they are monopolistic products, either because they are protected by an Intellectual Property Right –patent and/or data exclusivity—or simply because no other global company has been able to acquire the technology needed to copy them. Since patients with the ailments listed in Table 2 have no other treatment options available, the Colombian government has to buy these pharmaceutical products literally at the price defined by Big Pharma companies.

This scenario deteriorates even more if we consider the recent increase in the prevalence of high-cost diseases in Colombia, more concretely Cancer—which accounts for four of the top-ten bestseller pharmaceuticals and represents 43% of the costs of these products. In fact, malignant tumors–especially stomach for men, and breast for women—are the second cause of death in Colombia after heart and circulatory diseases.[37]

Likewise, together with the rising prevalence of Cancer, Colombia has witnessed a proliferation of Cancer patients' organizations. In fact, there are at least 39 active Cancer patients' organizations[38] and 15 (38%) of them offer some kind of 'legal advice' among their basic services to patients. Therefore, it is not a coincidence that in between

[36] Comparison made by El Tiempo (11 Feb 2010, p.1-8) and cited by the letter sent to the Colombian President by six civil society organizations. See http://www.med-informatica.net/OBSERVAMED/ReformaSistemaSalud/EmergenciaSocial2010/ES_MisionSalud_FMC_IFARMA_Carta_al_Presidente_Firma_Cardenal_16feb2010.pdf

[37] Instituto Nacional de Cancerología - INC, 2003.

[38] We refer here to the organizations that were identified and certified by the Social Mobilization Office at the National Cancer Institute, Bogotá.

2003 and 2008 Cancer was the most litigated --and expensive-- condition with a total 16.370 tutelas.[39]

5. Discussion

We accessed the Colombian Constitutional Court's search engine and looked for cases that mentioned the word RITUXIMAB or MABTHERA, a bio-tech pharmaceutical produced by ROCHE for the treatment of Cancer, among other conditions. We were interested in Mabthera® (Rituximab) since it is one of the most demanded pharmaceuticals by Colombian Tutela users. Because of the price assigned by Roche to this product, Rituximab is also a bio-tech pharmaceutical with a notorious impact on the overall costs of health-related litigiousness in Colombia. The average cost of a bottle of Mabthera 500mg concentrate[40] in Colombia is US$ 4.827, two times the price in Chile and 1.7 times the price in the US.[41]The ruling that we randomly selected (T-1214/08) from the resulting set was handed down by the Constitutional Court on December 5, 2008.[42] The plaintiff, Martín Suárez, demanded from his HMO --SANITAS-- the provision of a costly bio-tech pharmaceutical that he declared himself unable to purchase. Mr. Suárez stressed that the HMO decided not to deliver Rituximab arguing, first, that such pharmaceutical is not included in the mandatory health plan, and second, that Rituximab is not described by Colombia's Sanitary Authority (INVIMA) as the therapeutically-adequate medication for his type of eye Cancer (Orbital Pseudotumor). A

[39] Defensoria del Pueblo, Colombia (2006, 2009).
[40] Mabthera is and infusion ("drip") which is given directly into the veins. Usually when used alone in the treatment of Non-Hodgkin's lymphoma the complete treatment consists of four infusions (obtained from the Package leaflet: information for the user).
[41] In chile Mabthera's average price is US$ 2.000 (Chilecompra) and in the US it is US$ 2.500 (all-drugs-online).
[42] The ruling can be accessed at http://www.corteconstitucional.gov.co/relatoria/2008/t-1214-08.htm

first instance judge ruled in favor of the HMO, arguing that the plaintiff did not prove that Rituximab was a pharmaceutical indispensable for his subsistence; furthermore-- the first instance judge added--Colombia's sanitary agency did not include Rituximab as a medication with proved therapeutic effects for Mr. Suárez' type of tumor. In its decision, the Constitutional Court reiterated a long-standing precedent about access to high-cost medication excluded from the basic health plan. The Court concluded that in Mr. Suárez' case the provision of Rituximab was indispensable for his life and wellbeing. Furthermore, the Court stressed that the prescription of the Doctor outweighed the Sanitary Agency's concept about the therapeutic effect of the pharmaceutical. Thus, the Court ordered the HMO to provide Rituximab in the doses prescribed by the Doctor and encouraged the HMO to obtain a full reimbursement from the taxpayer-financed fund (Fosyga).

Ultimately, in Mr. Suarez' case three actors stand out as duty-bearers and right-holders. We identify two right-holders; on the one hand, the patient who has the right to life-saving medication, and on the other, the pharmaceutical company who has the right to the economic compensation for its prior Research and Development (R&D) investment. Conversely, the Colombian government is the only duty-bearer in the case. The government has at least two duties to comply with. The first, positive duty, assigned by the judge to the government is that of guaranteeing the patient's right to health by the provision of a costly bio-tech pharmaceutical. The second duty --that has negative and positive reverberations-- is defined by an international set of rules that envisaged monopoly rights –in the form of patents and/or data exclusivity—as the only mechanism to compensate the pharmaceutical industry for its R&D investment. According to this

duty, the government has the positive duty to pay for the full-price of the pharmaceutical as defined by Roche. It has also the negative duty to avoid any infringement on the IP Rights of Roche. Thus, by delivering the pharmaceutical to Mr. Suárez --as ordered by the judge-- and paying to Roche the full price invested in R&D, the government complied with both duties and satisfied the right-holders demands.

Nevertheless, this judicial outcome also means that by complying with both duties the government was neglecting an additional and equally important duty: *the Obligation to Protect*. According to the International Committee on Economic, Social and Cultural Rights, State Parties have the duty "… to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties…" Among the expected measures, the Committee includes the duty "to control the marketing of medical equipment and medicines by third parties."[43]

Two different reasons explain Colombia's failure to comply with the *duty to protect*. One is the notorious failure to regulate non-state entities "so as to prevent them from violating the right to health of others." As Sarah Joseph argues, failure to cap Big Pharma's prices may be an example of such a culpable omission.[44] The second reason is the intrinsic contradiction between the duty to protect and the commitment to endorse the global innovation regime by protecting IPRs (TRIPS) and paying high monopoly prices for Big Pharma pharmaceuticals.

As we have showed in this paper, the Colombian government dismantled the pharmaceutical prices' firewall system and by doing so misspent millions of dollars of taxpayer's money, endangering the general enjoyment of the right to health of its

[43] Art 12. ICESCR
[44] 2003.

population. But even if the Colombian government had effectively regulated the pharmaceutical market and obtained the best prices according to international standards, it is highly likely that the duty to protect would not have been met nonetheless, considering the unaffordable prices of biotech drugs charged worldwide by Big Pharma.[45] Therefore, had the Colombian government taken more seriously its duty to protect, the firewall erected at a global scale by Big Pharma Companies would had been unavoidable anyway. In the current global arrangement, relaxing IPRs protections through the enactment, for instance, of parallel imports or compulsory licensing policies, does not guarantee a significant increase in the likelihood of complying with the duty to protect by providing more affordable pharmaceuticals to needy sectors of the population. Indeed, many of the most expensive biotech drugs have no biosimilar available in the global market. Furthermore, Biotech companies are strongly lobbying around the world for policies that would harmonize sanitary registration requirements and procedures, all of which could raise powerful barriers to the entry of Biosimilars into global markets.[46]

The almost insurmountable obstacles faced by developing countries that try to comply with the duty to protect the right to health of its population from third parties, are particularly striking if we contrast them with Big Pharma's lack of significant correlative duties.

[45] In fact, high prices of biotech drugs are becoming a worrying issue even for developed high-income countries such as the US and the UK. In the U.S., a bipartisan group of lawmakers unveiled in 2009 proposal to allow government approval for cheaper copies of biotechnology medicines that cost as much as tens of thousands of dollars per year. According to Representative Henry Waxman, biotech drugs are the fastest-growing and most expensive part of the nation's prescription drug bill.
See http://www.reuters.com/article/idUSN11301138

[46] Biotech companies suggest that all Sanitary Authorities should require that all Biologics, not only the pioneer, present a complete set of clinical trials.

Big Pharma companies argue that "effective patent protection at home and abroad is vitally important to the pharmaceutical industry"[47] in order to keep innovation going. As Bernard Lemoine, director general of France's National Pharmaceutical Industry, pointed out, "I don't see why special effort should be demanded from the pharmaceutical industry. Nobody asks Renault to give cars to people who haven't got one."[48]

However, the argument of Big Pharma is less compelling if we consider, as Sarah Joseph invites us to do, that unlike cars, pharmaceuticals are mostly purchased by "trapped" individuals and by government health care sectors --i.e. by taxpayers. The fact that the pharmaceutical industry is arguably the most state-sponsored global market after the armament sector is, in itself, a highly plausible justification for a more active governmental intervention in Big Pharma's price-setting behavior. Furthermore, Big Pharma companies' price-setting behavior can be also put into question if one considers that its is not GDP-sensitive. On the contrary, developed countries are charged the same or even less than developing ones for life-saving pharmaceuticals. This is illustrated by the Colombian case, in which Big Pharma companies, taking advantage of regulatory weaknesses that were tailor-made for them, allocate prices for pharmaceuticals that exceed OECD levels.

It is true that some Big Pharma companies are experimenting with differential pricing. Among them, Glaxo Smith Kline, Brystol Myers Squib and Pfizer have taken the lead. Nevertheless, it is worth noting that although labeled as Corporate Social

[47] Gerald J. Mossinghoff, *Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide*, 2 J. L. & TECH. 307, 307 (1987). As cited by (Syed 2007)
[48] As cited by Joseph (2003)

Responsibility, these initiatives are essentially revenue-driven[49], and will therefore include not the most needed pharmaceuticals in developing countries, but only those that prove to be highly profitable.

Even though International Law has not yet evolved to the point of holding private actors, such as Big Pharma, accountable for the disastrous consequences of their pricing strategies, a global reassessment of the role of Big Pharma as duty-bearer is urgent. This reassessment should be both global and conducted at the institutional level. It should be global because no country has the leverage to constrain Big Pharma on its own. Additionally, the reassessment has to be conducted by an external --to Big Pharma-- institution, since leaving the task to Big Pharma's discretional Corporate Social Responsibility initiatives will backfire against the local right-holders and duty-bearers.

One of Henry Shue's conceptual categories, the idea of "mediating institutions", is instrumental to drive our argument home. Drawing from Shue's idea, we would like to conclude that in the current global arrangement we lack a global mediating institution that stands between global right-holders (Big Pharma) and local duty-bearers (governments) in order to allocate rights and duties in a more fair and effective way.[50]

Considering that the two main institutions responsible for allocating health related duties—the WTO and the WHO—have operated essentially in isolation, some authors have suggested that stronger interactions between them would be desirable.[51] Our argument goes beyond this. We consider that there are good reasons to advocate the merger of the existing institutions into a single global, mediating health institution

[49] As pointed out by GSK CEO Andrew Witty during the opening of a factory in Nashik, central India: "Our strategy is to grow our business in middle-income countries by increasing the volume of products we sell."
[50] See Shue (1988).
[51] See Lee et. al. (2009).

capable of allocating health-related rights and duties. In particular, a new Global Health and Trade Organization should be committed, among other things, to defining and enforcing the role of Big Pharma companies as duty-bearers. Rethinking Big Pharma's duties towards local right-holders and local duty-bearers is a relevant moral and legal challenge.

Table 1
Health Tutelas: Data Gathered from Colombia's Ombudsman Office

Year	Tutelas		Participation	Annual growth rate	
	Health	Total		Health	Total
1999	21.301	86.313	24,68%	-	-
2000	24.843	131.764	18,85%	16,63%	52,66%
2001	34.319	133.272	25,75%	38,14%	1,14%
2002	42.734	143.887	29,70%	24,52%	7,96%
2003	51.944	149.439	34,76%	21,55%	3,86%
2004	72.033	198.125	36,36%	38,67%	32,58%
2005	81.017	224.27	36,12%	12,47%	13,20%
2006	96.226	256.166	37,56%	18,77%	14,22%
2007	107.238	283.637	37,81%	11,44%	10,72%
2008	142.957	344.468	41,50%	33,31%	21,45%
TOTAL	**674.612**	**1.951.341**	**34,57%**		

Figure 1
Data construed by Observamed from Fosyga's Total and Tutela Pharmaceutical Expenditure
(US$ Millions)

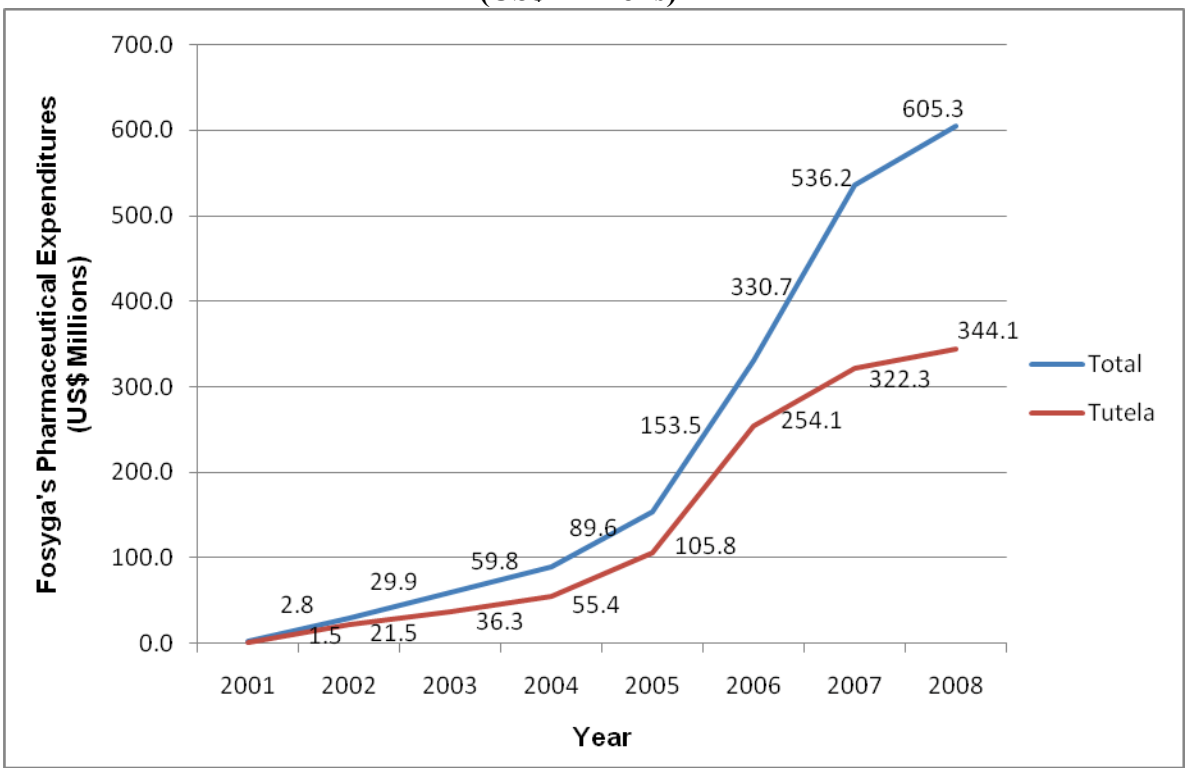

Table 2

Data Gathered from Observamed: Top Ten High-Cost Pharmaceutical Bestsellers

No.	Pharmaceutical Product	Active Principle	Excl.	Indication	Producer	Sales 2008 (US$)
1	MABTHERA 100 mg / 10 mL + 500 mg / 50 mL	RITUXIMAB	Yes	Cancer-Lymphoma Non Hodgkin	ROCHE	37,946,600
2	HUMIRA 40 mg	ADALIMUMAB	Yes	Immunosuppressant-Arthritis	ABBOTT	27,189,593
3	REMICADE 100 mg	INFLIXIMAB	Yes	Immunosuppressant-Crohn Disease	SCHERING_PLOUGH	25,662,007
4	GLIVEC 100 mg + 400 mg	IMATINIB		Cancer-Leuchemia	NOVARTIS	21,261,629
5	NOVOSEVEN 60 KUI + 120 KUI	VIIa FACTOR RECOMBINANT	Yes	Hemophilia VII A	AMAREY_NOVAMEDICAL	20,223,810
6	HERCEPTIN 440 mg / 50 mL	TRASTUZUMAB	Yes	Breast Cancer	ROCHE	18,646,563
7	BETAFERON	INTERFERON BETA 1B	Yes	Multiple Sclerosis	SCHERING_COL	16,654,781
8	ENBREL 25 mg + 50 mg	ETANERCEPT		Arthritis	WYETH	14,924,989
9	CELLCEPT 250 mg + 500 mg	MYCOPHENOLATE MOFETIL		Immunosuppressant-Trasplants	ROCHE	13,933,134
10	TEMODAL 5 mg + 20 mg + 100 mg + 250 mg	TEMOZOLOMIDE	Yes	Cancer-Glioblastom-Gliom-Melanom	SCHERING_PLOUGH	13,618,314
					TOTAL	**210,061,420**

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