PRICE COMPETITION MEETS DISCOUNT COMPETITION: HOW BAD REGULATORY DESIGN CAN AFFECT THE GENERICS PUBLIC POLICY AND REDUCE PATIENT SURPLUS

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Abstract: When the healthcare plans reimburse the hospitals for the full price cap, and at the same time not only do those hospitals negotiate massive discounts over the price cap with pharmaceutical companies, but also cash in those discounts in full and do not pass on to the patients any share of them, there is a strong incentive for those hospitals to purchase the drugs that have the highest price cap discounts, not rarely the drugs priced with the highest – not the lowest – market prices. This shift from price competition to discount competition can have notorious consequences for the generic drugs' low-price policy. In this article we explain why (i) the disconnect between (i.a) unrealistically high price caps and (i.b) the competitive price on a given market, (ii) the prevalence of the discounts policy over the price policy, (iii) the absence of the pass-on of a fair share of the discounts and (iv) the interference in the generics pricing policy by private discounts arrangements are likely to be the outcomes of bad regulatory design, and we offer options to realign economic incentives, overcome bad regulation and increase patient surplus.

Keywords: Price Cap; Discounts Policy; Price Policy; Generic Drugs; Reimbursement Policy.

Resumo: Quando os planos de saúde reembolsam os hospitais pelo preço-teto integral e, ao mesmo tempo, esses hospitais não apenas negociam descontos massivos sobre o preço-teto com as empresas farmacêuticas, mas também embolsam esses descontos integralmente sem repassar nenhuma parte deles aos pacientes, cria-se um forte incentivo para que esses hospitais adquiram os medicamentos com os maiores descontos sobre o preço-teto. Não raramente, esses medicamentos são os que possuem os preços de mercado mais altos — e não os mais baixos. Essa mudança da competição por preços para a competição por descontos pode ter consequências notórias para a política de baixos preços de medicamentos genéricos. Neste artigo, explicamos por que (i) a desconexão entre (i.a) preços-teto irrealisticamente altos e (i.b) o preço competitivo em um determinado mercado, (ii) a prevalência da política de descontos sobre a política de preços, (iii) a ausência de repasse de uma parcela justa dos descontos e (iv) a interferência na política de precificação de genéricos por arranjos privados de descontos são provavelmente resultados de um desenho regulatório inadequado. Também oferecemos opções para realinhar os incentivos econômicos, superar a má regulação e aumentar o benefício para os pacientes.

Palavras-chave: Teto de Preços; Política de Descontos; Política de Preços; Medicamentos Genéricos; Política de Reembolso.

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Summary: 1 When Regulation Fails to Offer a Fair Price Cap Regualtion; 2 The Perverse Incentives Hidden in Drug´s Price Cap Discounts; 3 When the Courts Recognize the Hospital´s Right to Cash in Price Cap Discounts; 4 Competition Problems; 5 Regulatory Solutions; 6 Final Remarks; 7 Bibliographic References.

1 When Regulation Fails to Offer a Fair Price Cap Regulation

Pharmaceutical companies (either laboratories or distributors) that sell to any kind of consumer in the Brazilian market – be it an intermediary or an end consumer, a corporation or an individual – are subject to price cap regulation. Price cap regulation was introduced in 2003 by Law 10,742 as a means to increase broad access to healthcare2 and not only includes a maximum price for every prescription drug, but also affords extra discounts for both (i) generic drugs in general and (ii) public procurement under specific circumstances, like court orders and priority programs of the Ministry of Health.

Price cap effectiveness can be deeply affected by bad regulation, though. The larger the gap between the regulated price and the competitive price3, the less effective the price cap is. And that goes both ways: The price cap cannot be (i) so high that it does not inflict any pressure on the costs of the monopolist or oligopolist, or (ii) so low that it does not offer sufficient economic incentives for a timely entry into the market. In this article, we address one situation where bad regulatory design led to unrealistically high price caps.

One way to identify price cap distortions is precisely by looking for wholesale or retail discounts. Depending on the magnitude of the discounts, neither anticompetitive fidelity rebates nor gains of scale or scope in sales for large or monopsonistic buyers can justify them, leaving little room to argue against the existence of an overestimation of the price cap by the regulatory authorities. When pharmaceutical companies market drugs at prices that account for a fraction of their price caps, there is evidence that the regulatory body has not effectively priced the drug at the competitive level.

Price caps can be distorted for at least two reasons. First, the entrance price cap may have been wrongly estimated. We usually expect bad estimations to be the consequences of information asymmetry or human error, but they can also be the outcomes of capture or bad public policy.

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[2] BRASIL. **E.M. n.º 28**. Brasília-DF: Presidência da República, 26 jun. 2003. Disponível em: https://www.planalto.gov.br/CCIVIL_03/Exm/2003/EMI28-CCV-MS-MF-MJ-03.htm. Acesso em: 20 jun. 2024.

[3] The marginal cost, here interpreted as including the minimum compensation that the firm needs to keep investing in drug production, including a higher premium during patent protection.

Second, even when a price cap has been correctly established, the market value of the technology can be appreciated or depreciated without the proper rebalance by the regulatory authority. Outdated market value is usually the consequence of bad regulation, but can also be determined by lack of data (like sector specific input inflation) or capture. Capture usually focuses on avoiding price depreciation, particularly the gradual depreciation of the market value of patented drugs.

Pricing problems can be magnified when the regulator lacks the appropriate tools to make corrections along the way and update the price caps after the original decision is issued by the pricing regulatory authority. In that case, the market is given an incentive to forge long term strategies, including contract and tax arrangements, that might weaken competition on the merit. Not surprisingly, price cap distortions can distort regulatory incentives. When the gap between the regulatory price cap and the competitive price is way too large, bad regulation can, unintendedly or not, make it possible for pharmaceutical companies to offer unrealistically high price cap discounts. In this paper, we are interested in how those discounts can distort a generic drugs' public policy that aims at making drugs available at low prices, shifting the successful model of price competition into a model of discounts competition.

2 The Perverse Incentives Hidden in Drug´s Price Cap Discount

Under certain conditions, market players like hospitals and clinics can understand that price cap discounts offered by the pharmaceutical companies have more value to them than access to lower prices. When healthcare plans reimburse hospitals and clinics for a flat amount – the full regulated price cap4 – and hospitals cash in the whole discount offered by the pharmaceutical companies, the buyers (hospitals and clinics) have a strong incentive to purchase drugs that have the highest discounts, not rarely the drugs priced with the highest –

[4] In Brazil, healthcare plans reimburse hospitals and clinics under fee-for-service regulation. Even though federal drug price regulation forbids hospitals from cashing in resale margins or charging healthcare plans any amount higher than the price actually paid to pharmaceutical companies (Resolution CMED N. 3 of 2009, as interpreted by Interpretative Orientation N. 5 of 2009), healthcare plan regulation seem more comfortable to accept that the parties mutually agree that hospitals and clinics charge healthcare plans for more than what they actually paid, as long as the margins cashed in are discounts offered by the pharmaceutical companies over the drug price cap (Normative Resolution ANS N. 241 of 2010, as amended by Normative Resolution ANS N. 503 of 2022, and collective negotiation involving the ANS and the private sector representing both healthcare plans and the hospitals). See: GRUPO DE TRABALHO SOBRE REMUNERAÇÃO DOS HOSPITAIS. **Sistemáticas de Remuneração dos Hospitais que atuam na Saúde Suplementar: Diretrizes e Rumos**. Rodada do Rio de Janeiro, Rio de Janeiro, junho 2010, p. 1-25. Disponível em: https://www.gov.br/ans/pt-br/arquivos/acesso-a-informacao/participacao-da-sociedade/camaras-e-grupos-tecnicos/camaras-e-grupos-tecnicos-anteriores/grupo-tecnico-externo-de-orteses-proteses-e-materiais-especiais/grupo5_orteses_proteses_materiais_especiais_rodadarj_2010.pdf. Acesso em: 25 jul. 2024.

not the lowest – regulated price caps or even the highest – not the lowest – actual market prices. Because generic drugs are expected to have the lowest market prices, laboratories that sell generic drugs are as consequence expected to be the most affected by this market abnormality that, as we shall see, is determined by bad regulatory design.

Generic drugs are expected to offer lower discounts than patented drugs because their bottom line is also lower: The Brazilian federal authority that sets and oversees drugs prices (CMED) determines that the price cap of generic drugs in Brazil is at least thirty-five percent lower than the cap for the innovative drug. At the same time, because generic drugs only enter the market after the relevant patent expires, it is expected that, by the time that the generics' entrance is allowed, (i) innovative drugs' laboratories will already have made recoupment and (ii) will be able to cut the price of the innovative drugs to compete with the prices of their generic version.

Because in Brazil the price caps of innovative drugs have not been cut by the regulatory authority to reflect the depreciation of the market value of their patents, innovative drugs' laboratories offer significant discounts that roughly correspond to at least thirty-five percent of their price cap when they want to compete in price with their generic version. Conversely, because generic drugs price caps are set by CMED having in mind their abbreviated and much cheaper process of registration, we expect that generics' price caps encompass much lower margins and approach marginal costs. As consequence, generic drugs, particularly those that have just entered the market, are expected to have little room to compete in discounts with innovative drugs whose patent protections expired.

Because price cap regulation was forged so that the generic drugs' lower prices would incentivize price cap discounts by innovative pharmaceutical companies that wanted to compete in price with their generic version, discounts should have beneficial consequences to price competition after the expiration of the patent of the innovative drug. It is the distortion of those incentives by a sector whose regulation depends on the complex alignment of at least three regulatory bodies in Brazil – CMED (the national drug pricing authority), ANVISA (the national drug regulatory agency) and ANS (the national healthcare plan regulatory agency) – that shifted those incentives when price cap discounts to hospitals come into play.

When the full reimbursement of the price cap by healthcare plans and the intermediary's ability to cash in the full amount of the discount make price cap discounts look more attractive than low prices to hospitals and clinics, then the innovative drugs labs have a clear head start over the generic drugs ones in hospital procurement. Because healthcare plans reimburse hospitals

and clinics for the full price cap of the medication used in authorized procedures – regardless of their prices -, hospitals and clinics that buy drugs with discounts over the price cap have strong economic incentives to buy those drugs that offer the highest discount over the price cap that will be reimbursed by the healthcare plan and cash in the discount in full.

The following mathematical model sums up the finding that, given the full reimbursement of the price cap by the healthcare plans, hospitals will choose the drug that offers the highest discount:

(FFS = MPcap) | [(MPcap - P) > 0] => Hc = max (MPcap - P)

Where:
HC = hospital/clinic choice
MPcap = regulated price cap of the medication
max (MPcap - P) = maximum discount over the price cap
FFS = fee-for-service reimbursement
P = price after discount

Because the healthcare plans reimburse the drugs' price caps in full, the rational behavior of the hospitals is, coeteris paribus, to look for drugs offering discounts over the price cap and – among those – to purchase the drugs with the highest discount. The logic lies in that, when the price cap is reimbursed in full, any discount over the price cap becomes a new source of revenue, and the higher the discount, the higher the revenue.

At the same time, because – as mentioned earlier – the generic drugs regulation itself was designed to bring prices down by fixing significantly lower price caps to generic drugs, generic drugs have a smaller room to offer price discounts.

As consequence, generic drugs do not stand on equal foot with non-generic drugs when large price cap discounts become more important than low market prices. Therefore, by opting for the highest discount, hospitals and clinics are usually choosing to buy non-generic drugs, whose margins are in general expected to be lower than the margins of the innovative drug. Because the margins of generic drugs are dire, their chances of expressive discounts are also lower. In other words, the same regulation that makes generic drugs fit to price competition has, with the help of bad regulatory design, made generic drugs unfit to compete on equal foot in a world ruled by price cap discounts.

The following chart offers a visual example of a situation where lower generic prices are not as attractive as higher margins offered by innovative drugs. As one can see, the larger the margin, the more attractive that drug is to the hospital.

Table 1. Drug Price Cap, Average Market Price and Price Discount

Lab	Drug	Pcap	Avg DP	Discount
	Innovative drug	0,29	0,15	0,14
	Other patented drug	0,28	0,14	0,14
	Generic drug	0,15	0,10	0,05

Source: author's own elaboration, based on lawsuits and on the SAMMED database.

As we shall see in the next section, CMED has condemned that hospitals have not passed on any share of the price cap discounts to the patients and have cashed in what should have become lower prices and patient surplus. CMED has also claimed that it is against the law to profit on what it has interpreted to be a (construed) resale of drugs from the hospitals and clinics to the patient via healthcare plans which has distorted the market incentives towards the purchase of the drugs with the highest prices. We shall also see that hospitals have, with a considerable degree of success, filed lawsuits in order to have their rights to cash in the discounts affirmed in a court of law. At the same time, CMED has no tool yet to review and adjust the price caps along the way – which, if implemented, would be a powerful way to lower the payoff of a discounts policy vis-à-vis a low-price policy.

One specific aspect makes the aforementioned economic incentives of the Brazilian regulation – a combination of both bad regulatory design and low public enforcement – a major threat to the generics policy. Because hospitals' and clinics' agents have low information asymmetry regarding drugs, procurement of those institutions is expected – everything else being equal – to rely less on the brand of the drug and more on its proven scientific therapeutic benefits, making hospitals and clinics more prone to buy generic drugs having in mind their budgetary constraints. Because hospitals and clinics are also the main beneficiaries of this regulatory imbroglio that has turned price cap discounts more relevant than the availability of low prices, it is clear that generic drugs are losing an important market, showing that the shift from a price policy to a discounts policy represents a significant rise in the barriers to the entry of generic drugs. The problem is more egregious in markets where the drug or a specific formulation of that drug is limited to hospital use or depends heavily on it.

Finally, passing on a fair share of the price cap discounts to the patient alone may not solve the regulatory distortion against the generic drugs. In fact, where price cap

overestimations are too great, the pass-on – without a joint effort to align the price cap with the competitive price – may only consolidate the discounts policy and eliminate the incentives to buy generic drugs.

3 When the Courts Recognize the Hospitals' Right to Cash in Price Cap Discounts

Anvisa's Drug Market Monitoring System (SAMMED) data offers a unique opportunity to identify the gap between price caps and the average price at which a drug is actually sold on the market. Due to confidentiality restrictions, SAMMED data are not public and cannot be replicated in this study. Our immersion over the data5 allows us to claim that important drugs have been sold at discounts that are higher than seventy percent of the price cap.

Access to those data is not essential for the purpose of this study, though. Prize winner investigation by Amanda Rossi6 offers examples of discounts that amount to more than seventy percent of the price cap. Although the article limited the investigation to retail prices in drugstores, it offers evidence of the same reality we found looking at SAMMED data: That the market of drugs has unrealistically high price caps and offers room for massive discounts.

Two other sources confirm both (i) the existence of the discounts to the hospitals and to the clinics alike (ii) as well as the full cash-in of the discounts by said hospitals and clinics (and, as consequence, the absence of the pass-on of a fair share of the discounts to the patient). First, Resolution CMED N. 2 of 2018 – which sets forth that both hospitals and clinics that charged either patients or healthcare plans more than what they paid the pharmaceutical companies for the medication (the final price after the discounts are applied) should be subject to fines (Article 5, II, c) – was issued as a response to actual market behavior. The command considered that by not passing on the full discount to the patient or to the plan, hospitals and clinics were reselling the drugs to those very patients and healthcare plans (construed resale of drugs) – a behavior already vetoed by Resolution CMED N. 3 of 2009, as interpreted by Interpretative Orientation N. 5 of 2009. In fact, both Resolution CMED N. 3 of 2009 and

[5] For the purpose of this paper, the author had legally authorized access to the SAMMED data.
[6] ROSSI, Amanda. **O que a farmácia sabe sobre mim**? Disponível em: https://noticias.uol.com.br/reportagens-especiais/o-que-a-farmacia-sabe-sobre-mim/#page1. Acesso em: 25 jul. 2024. / 'O DESCONTO NÃO É REAL': o que está por trás do CPF que pedem na farmácia. **UOL São Paulo**, 29 fev. 2024. Disponível em: https://noticias.uol.com.br/cotidiano/ultimas-noticias/2024/02/29/o-desconto-nao-e-real-o-que-esta-por-tras-do-cpf-que-pedem-na-farmacia.htm. Acesso em: Acesso em: 25 jul. 2024.

Interpretative Orientation N. 5 of 2009 are derivations CMED's understanding that Law N. 5.991 of 1973 prohibited hospitals from charging for the act of dispensing medication.

Second, hospitals have insurged against Resolution CMED N. 2 of 2018 – that revisits Resolution CMED N. 3 of 2009 – and filed over thirty lawsuits7 challenging the core of the regulation, claiming freedom of enterprise and that the cash-in of the discounts over the price caps is necessary to cover all the (storing, manipulation, transportation, tracking) costs involved in the treatments where the drugs were used. The following table offers a view of the decisions in those claims where the courts have already issued injunctions.

Table 2. Hospitals' Lawsuits to Affirm their Right not to Pass on the Discounts

DOCKET - COMPLAINANT	AWARD
1009788-74.2019.4.01.3400 - Aliança Instituto de Oncologia S/A et allia.	Preliminary injunction granted.
5030249-44.2018.402.5101 - Associação de Hospitais do Estado do Rio de Janeiro.	Preliminary injunction not granted.

[7] 1009788-74.2019.4.01.3400 (Aliança Instituto de Oncologia S/A e outros); 1043635-96.2021.4.01.3400 (Angara Oncologia e Participações S/A); 1007185-53.2018.4.01.3500(Associação dos Hospitais do Estado de Goiás (AHEG)); 5030249-44.2018.402.5101 (Associação de Hospitais do Estado do Rio de Janeiro (AHERJ)); 1006919-41.2019.4.01.3400 (Associação de Hospitais do Estado do Rio de Janeiro (AHERJ)); 1021758-08.2018.4.01.3400 (Associação dos Hospitais do Estado de São Paulo (AHESP) e outra); 1005862-94.2019.4.01.3300 (Associação dos Hospitais e Serviços de Saúde do Estado da Bahia); 5001401-93.2019.4.03.6100 (Associação Hospitalar Filhas de Nossa Senhora do Monte Calvário); 1018885-35.2018.4.01.3400 (Associação Nacional de Hospitais Privados); 1007716-17.2020.4.01.4100 (Casa de Saúde Bom Jesus Ltda e outros); 5008030-30.2019.4.04.7208/SC (Clínica de Neoplasias Litoral Ltda.); 5008502-83.2018.4.04.7202 (Cooperativa de Trabalho Médico da Região Oeste Catarinense - UNIMED CHAPECÓ); 1022737-67.2018.4.01.3400 (Cooperativa de Trabalho Médico - UNIMED GURUPI); 1022735-97.2018.4.01.3400 (Cooperativa de Trabalho Médico - UNIMED PALMAS); 5024511-75.2018.4.02.5101/RJ (Federação das Misericórdias e Entidades Filantrópicas e Beneficentes do Estado do Rio de Janeiro (FEMERJ)); 1019156-10.2019.4.01.3400 (Federação das Santas Casas e Hospitais Beneficentes do Estado de São Paulo (FEHOSP)); 5065398-64.2018.4.04.7100 (Federação das Santas Casas e Hospitais Beneficentes Religiosos e Filantrópicos do Estado do Rio Grande do Sul (FESCFILRS) e outro); 5012898-67.2018.4.02.5001 (Federação das Santas Casas e Hospitais Filantrópicos do Estado do Espírito Santo (FEHOFES)); 1028980-27.2018.4.01.3400 (Federação dos Hospitais e Estabelecimentos de Saúde do Rio Grande do Sul (FEHOSUL) e outros); 5039536-03.2018.4.04.7000 (Federação dos Hospitais e Estabelecimentos de Serviços de Saúde no Estado do Paraná (FEHOSPAR) e outros); 1010324-51.2021.4.01.4100 (Hospital HCC de Ariquemes Ltda EPP); 5003634-54.2019.4.03.6103 (Irmandade da Santa Casa de Misericórdia de São José dos Campos); 033033-80.2020.4.01.3400 (Núcleo de Hematologia e Transplante de Medula Óssea de Minas Gerais Ltda e Pró-Onco Centro de Tratamento Oncológico SS Ltda); 1020812-36.2018.4.01.3400 (Sindicato Brasiliense de Hospitais, Casas de Saúde e Clínicas (SBH) e outros); 1043948-28.2019.4.01.3400 (Sindicato dos Estabelecimentos de Serviços de Saúde do Estado de Alagoas (SINDHOSPITAL) e outros); 0000009-16.2011.4.02.5001 (Sindicato dos Estabelecimentos de Serviços de Saúde do Estado do Espírito Santo (SINDHES)); 1008892-31.2019.4.01.3400 (Sindicato dos Estabelecimentos de Serviços de Saúde do Estado do Pará (SINDESPA) e outros); 5024271-69.2018.4.03.6100 (Sindicato dos Hospitais, Clínicas, Casas de Saúde, Laboratórios de Pesquisa e Análises Clínicas no Estado de São Paulo (SINDHOSP) e outros); 5029410-19.2018.4.02.5101 (Sindicato dos Hospitais, Clínicas e Casas de Saúde do Município do Rio de Janeiro (SINDHRIO)); 1023105-76.2018.4.01.3400 (Sindicato dos Hospitais e Estabelecimentos de Serviços de Saúde da Baixada Fluminense (SINDHESB)); 1005566-63.2019.4.01.3400 (Sindicato dos Estabelecimentos de Serviços de Saúde do Sul de Santa Catarina (SINESSUL) e outros).

1021758-08.2018.4.01.3400 - Associação dos Hospitais do Estado de São Paulo (AHESP) et allia.	Preliminary injunction not granted.
1005862-94.2019.4.01.3300 - Associação dos Hospitais e Serviços de Saúde do Estado da Bahia.	Preliminary injunction granted.
5001401-93.2019.4.03.6100 - Associação Hospitalar Filhas de Nossa Senhora do Monte Calvário.	Preliminary injunction granted. Court award confirming the injunction.
1018885-35.2018.4.01.3400 - Associação Nacional de Hospitais Privados (ANAHP).	Preliminary injunction granted. Court award confirming the injunction.
1007716-17.2020.4.01.4100 - Casa de Saúde Bom Jesus Ltda et allia.	Preliminary injunction not granted.
5008030-30.2019.4.04.7208/SC - Clínica de Neoplasias Litoral Ltda.	Preliminary injunction not granted. Court award granting the injunction.
5008502-83.2018.4.04.7202 - Cooperativa de Trabalho Médico da Região Oeste Catarinense - UNIMED CHAPECÓ.	Preliminary injunction granted. Court award confirming the injunction.
1022737-67.2018.4.01.3400 - Cooperativa de Trabalho Médico - UNIMED GURUPI.	Preliminary injunction granted.
1022735-97.2018.4.01.3400 - Cooperativa de Trabalho Médico - UNIMED PALMAS.	Preliminary injunction granted. Court award confirming the injunction.
5024511-75.2018.4.02.5101/RJ - Federação das Misericórdias e Entidades Filantrópicas e Beneficentes do Estado do Rio de Janeiro (FEMERJ).	Preliminary injunction granted. Court award not confirming the injunction.
1019156-10.2019.4.01.3400 - Federação das Santas Casas e Hospitais Beneficentes do Estado de São Paulo (FEHOSP).	Preliminary injunction granted.
5065398-64.2018.4.04.7100 - Federação das Santas Casas e Hospitais Beneficentes Religiosos e Filantrópicos do Estado do Rio Grande do Sul (FESCFILRS) et ali.	Preliminary injunction not granted. Court award reaffirming preliminary decision (not granting the injunction).
5012898-67.2018.4.02.5001 - Federação das Santas Casas e Hospitais Filantrópicos do Estado do Espírito Santo (FEHOFES).	Preliminary injunction granted. Court award not confirming the injunction.
1028980-27.2018.4.01.3400 - Federação dos Hospitais e Estabelecimentos de Saúde do Rio Grande do Sul (FEHOSUL) et ali.	Preliminary injunction granted. Court award confirming the injunction.
5039536-03.2018.4.04.7000 - Federação dos Hospitais e Estabelecimentos de Serviços de Saúde no Estado do Paraná (FEHOSPAR) et ali.	Court award granting the injunction.
1010324-51.2021.4.01.4100 - Hospital HCC de Ariquemes Ltda EPP.	Preliminary injunction not granted.

5003634-54.2019.4.03.6103 - Irmandade da Santa Casa de Misericórdia de São José dos Campos.	Preliminary injunction not granted. Court award reaffirming preliminary decision (not granting the injunction).
033033-80.2020.4.01.3400 - Núcleo de Hematologia e Transplante de Medula Óssea de Minas Gerais Ltda/Pró-Onco Centro de Tratamento Oncológico SS Ltda.	Preliminary injunction granted.
1020812-36.2018.4.01.3400 - Sindicato Brasiliense de Hospitais, Casas de Saúde e Clínicas (SBH) et ali.	Preliminary injunction granted.
1043948-28.2019.4.01.3400 - Sindicato dos Estabelecimentos de Serviços de Saúde do Estado de Alagoas (SINDHOSPITAL) et ali.	Preliminary injunction not granted. Court award granting the injunction.
0000009-16.2011.4.02.5001 - Sindicato dos Estabelecimentos de Serviços de Saúde do Estado do Espírito Santo (SINDHES).	Preliminary injunction not granted. Court award reaffirming preliminary decision (not granting the injunction).
1008892-31.2019.4.01.3400 - Sindicato dos Estabelecimentos de Serviços de Saúde do Estado do Pará (SINDESPA) et ali.	Preliminary injunction not granted.
5024271-69.2018.4.03.6100 - Sindicato dos Hospitais, Clínicas, Casas de Saúde, Laboratórios de Pesquisa e Análises Clínicas no Estado de São Paulo (SINDHOSP) et ali.	Preliminary injunction granted. Court award confirming the injunction.
5029410-19.2018.4.02.5101 - Sindicato dos Hospitais, Clínicas e Casas de Saúde do Município do Rio de Janeiro (SINDHRIO).	Preliminary injunction not granted. Court award reaffirming preliminary decision (not granting the injunction).
1023105-76.2018.4.01.3400 - Sindicato dos Hospitais e Estabelecimentos de Serviços de Saúde da Baixada Fluminense (SINDHESB).	Preliminary injunction granted. Court award confirming the injunction.
1005566-63.2019.4.01.3400 - Sindicato dos Estabelecimentos de Serviços de Saúde do Sul de Santa Catarina (SINESSUL) et ali.	Preliminary injunction granted.

Source: author's own elaboration, based on information provided by CMED.

As one can see, Table 2 shows that many courts have granted injunctions or awarded pro-complainant final decisions that leave room to the understanding that Section 4 (XV) of Law N. 5.991 of 1973 in fact allows that drug dispensers fully cash in the discounts negotiated with the pharmaceutical companies. On the other hand, many others have also mentioned that ANS[8] does not forbid hospitals or clinics from charging for the services connected to the use of the drugs they purchased to medicate patients (storing, manipulation, transportation,

[8] See Resolution ANS N. 363 of 2014.

tracking), but asserting such clearance that does not amount to admitting that hospitals could charge for (or trade) the drugs and therefore afford not to fully pass on the discounts to the patient.

There is at least one decision9 specifying that hospitals and clinics cannot substitute the full cash-in of drug discounts – which that court specifically found to be illegal in Brazil – for the licit charges over accessory hospital services like storing, selection, fractioning, transportation, among others. In other words, the court distinguished the flat prices charged by the hospitals for dispensing medication, which are typically horizontal (uniform for similar procedures) and depend basically on the complexity of the task, from the non-linear amount cashed in after price cap discounts. Price cap discounts might not even be the same for identical procedures and diseases, insofar as they do not necessarily reflect the complexity of the accessory service, but the price of the relevant drug elected to be used in the medical procedure – which might vary from hospital to hospital and from physician to physician.

Although those lawsuits are still being litigated or under appeal, it is already possible to see how some courts have been reluctant to render decisions that might affect the financial health of a sector that has already been subject to massive consolidation over the last decade. In fact, although it is true that the sector has been subject to major structural changes – Brazil's competition commission (CADE) has analyzed two hundred and eighty-five mergers from 2003 to 2020 -, only three mergers have been challenged by the national antitrust authority10.

By cashing in the full price cap discount – and not passing on at least part of the patient surplus to the healthcare plan (and indirectly to the payers11) or to the out-of-pocket patient -, hospitals and clinics have increased patient spending with health services, lowering patient surplus and welfare. But, because a shift towards the pass-on alone is not enough to restore the appeal of the generic drugs' pricing policy, the regulatory framework must be addressed to halt the growing importance of the discounts policy and increase price competition, thus building a sustainable competitive environment that lowers prices and increases patient surplus.

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[9] Docket N. 0000009-16.2011.4.02.5001 (Sindicato dos Estabelecimentos de Serviços de Saúde do Estado do Espírito Santo (SINDHES)).

[10] BRASIL. Ministério da Justiça e Segurança Pública. Conselho Administrativo de Defesa Econômica. **Atos de concentração nos mercados de planos de saúde, hospitais e medicina diagnóstica** (Edição revista e atualizada) (Série Cadernos do Cade). Brasília-DF: Departamento de Estudos Econômicos (DEE) – Cade, jan. 2022, p. 1-108. Disponível em: https://cdn.cade.gov.br/Portal/centrais-de-conteudo/publicacoes/estudos-economicos/cadernos-do-cade/Cadernos-do-Cade_AC-saude-suplementar.pdf. Acesso em: 25 jul. 2024.

[11] When the surplus is passed on to the healthcare plan, we expect that lower drug prices will lead to lower annual adjustments in the prices of plans.

4 Competition Problems

As shown above, when healthcare plans reimburse hospitals and clinics for the full price cap, higher margins of discount become more important than lower prices for the hospitals and clinics. That is so because the cash-in of the margins creates a new source of revenue to the hospitals and to the clinics alike, while purchases whose discounts are entirely passed on bring them no profit at all.

Three other factors come into play when one analyzes whether hospitals and clinics will be able to cash in the full discount, though: Patient awareness, patient price-elasticity and the level of competition among hospitals.12

The hospitals' ability to cash in the price cap discounts in full is inversely proportional to both the degree of patient awareness of the benefits that they – even indirectly – can extract from price discounts and to the economic relevance of price discounts at all on patient choice. It is only when the patients are aware that they can benefit from the pass-on and they consider that the amount of the pass-on is significant enough to justify fighting for it that the degree of competition on the hospital and on the healthcare plan markets becomes relevant.

In general, the price of the medication in hospital care only matters to the patients that afford out-of-pocket expenses. Even so, hospitals or clinics might still cash in the whole price cap discount depending on multiple factors, like: (a) how transparent the pricing policy is; (b) how much the drug accounts for in total cost; (c) how significant is the co-payer's share in the costs; (d) the degree of competition on the market; and (e) the quality of the services of the competitors.

If the co-payer has no opportunity to disaggregate the costs she will have to pay for; if the drug accounts for only a small share of the total cost of treatment; if all the co-payer's options are using the discount policy or if the quality of the other options is significantly lower, hospitals and clinics might be able to cash in the full price cap discount even when the co-payer is price elastic.

When hospitals and clinics prioritize price cap discounts over lower costs, one observes the substitution of price competition, turning the market less interesting to mavericks

[12] Competition among healthcare plans also counts when the regulation does not set the price cap as the fee for the service, which is not the case in Brazil. See GRUPO DE TRABALHO SOBRE REMUNERAÇÃO DOS HOSPITAIS. **Sistemáticas de Remuneração dos Hospitais que atuam na Saúde Suplementar: Diretrizes e Rumos**. Rodada do Rio de Janeiro, Rio de Janeiro, junho 2010, p. 1-25. Disponível em: https://www.gov.br/ans/pt-br/arquivos/acesso-a-informacao/participacao-da-sociedade/camaras-e-grupos-tecnicos/camaras-e-grupos-tecnicos-anteriores/grupo-tecnico-externo-de-orteses-proteses-e-materiais-especiais/grupo5_orteses_proteses_materiais_especiais_rodadarj_2010.pdf. Acesso em: 25 jul. 2024.

and innovators that should win competition by managing to be more cost efficient. Because price caps are much higher for the innovative drugs, it is regulation – not market efficiency – that will determine who wins the competition for hospital procurement among pharmaceutical companies, creating what we call path dependence.

Also, if price competition is weakened, so are the incentives to the entry of generic drugs. The consequence of the dominance of (high) discounts policy over (low) pricing policy is bad regulation crowding out innovation, patient surplus and lower prices. It also concentrates the market around innovative pharmaceutical companies, narrowing the room that the generic drugs' industry has to develop. By affecting the generic drugs' industry, we expect that lower competition within the pharmaceutical industry and lower countervailing power to negotiate with healthcare plans will increase the pressure to increase prices. Also, by increasing the costs for the development of a generic drugs' market in Brazil, a weakened price competition poses a threat to the generic drugs' public policy that is central to the sustainability of Brazil's Unified Health System.

Finally, the full cash-in of the margin of discount by hospitals also comes with tax asymmetry and unlevel playing field. Hospital invoices collected in lawsuits[13] evidence that

[13] 1009788-74.2019.4.01.3400 (Aliança Instituto de Oncologia S/A e outros); 1043635-96.2021.4.01.3400 (Angara Oncologia e Participações S/A); 1007185-53.2018.4.01.3500(Associação dos Hospitais do Estado de Goiás (AHEG)); 5030249-44.2018.402.5101 (Associação de Hospitais do Estado do Rio de Janeiro (AHERJ)); 1006919-41.2019.4.01.3400 (Associação de Hospitais do Estado do Rio de Janeiro (AHERJ)); 1021758-08.2018.4.01.3400 (Associação dos Hospitais do Estado de São Paulo (AHESP) e outra); 1005862-94.2019.4.01.3300 (Associação dos Hospitais e Serviços de Saúde do Estado da Bahia); 5001401-93.2019.4.03.6100 (Associação Hospitalar Filhas de Nossa Senhora do Monte Calvário); 1018885-35.2018.4.01.3400 (Associação Nacional de Hospitais Privados); 1007716-17.2020.4.01.4100 (Casa de Saúde Bom Jesus Ltda e outros); 5008030-30.2019.4.04.7208/SC (Clínica de Neoplasias Litoral Ltda.); 5008502-83.2018.4.04.7202 (Cooperativa de Trabalho Médico da Região Oeste Catarinense - UNIMED CHAPECÓ); 1022737-67.2018.4.01.3400 (Cooperativa de Trabalho Médico - UNIMED GURUPI); 1022735-97.2018.4.01.3400 (Cooperativa de Trabalho Médico - UNIMED PALMAS); 5024511-75.2018.4.02.5101/RJ (Federação das Misericórdias e Entidades Filantrópicas e Beneficentes do Estado do Rio de Janeiro (FEMERJ)); 1019156-10.2019.4.01.3400 (Federação das Santas Casas e Hospitais Beneficentes do Estado de São Paulo (FEHOSP)); 5065398-64.2018.4.04.7100 (Federação das Santas Casas e Hospitais Beneficentes Religiosos e Filantrópicos do Estado do Rio Grande do Sul (FESCFILRS) e outro); 5012898-67.2018.4.02.5001 (Federação das Santas Casas e Hospitais Filantrópicos do Estado do Espírito Santo (FEHOFES)); 1028980-27.2018.4.01.3400 (Federação dos Hospitais e Estabelecimentos de Saúde do Rio Grande do Sul (FEHOSUL) e outros); 5039536-03.2018.4.04.7000 (Federação dos Hospitais e Estabelecimentos de Serviços de Saúde no Estado do Paraná (FEHOSPAR) e outros); 1010324-51.2021.4.01.4100 (Hospital HCC de Ariquemes Ltda EPP); 5003634-54.2019.4.03.6103 (Irmandade da Santa Casa de Misericórdia de São José dos Campos); 033033-80.2020.4.01.3400 (Núcleo de Hematologia e Transplante de Medula Óssea de Minas Gerais Ltda e Pró-Onco Centro de Tratamento Oncológico SS Ltda); 1020812-36.2018.4.01.3400 (Sindicato Brasiliense de Hospitais, Casas de Saúde e Clínicas (SBH) e outros); 1043948-28.2019.4.01.3400 (Sindicato dos Estabelecimentos de Serviços de Saúde do Estado de Alagoas (SINDHOSPITAL) e outros); 0000009-16.2011.4.02.5001 (Sindicato dos Estabelecimentos de Serviços de Saúde do Estado do Espírito Santo (SINDHES)); 1008892-31.2019.4.01.3400 (Sindicato dos Estabelecimentos de Serviços de Saúde do Estado do Pará (SINDESPA) e outros); 5024271-69.2018.4.03.6100 (Sindicato dos Hospitais, Clínicas, Casas de Saúde, Laboratórios de Pesquisa

those institutions do not outline how much out of the total amount charged for the service corresponds to what patients or health plans are actually paying for the drugs, leaving little room for patients or patients' associations to complain. The proper disaggregation of the costs of hospitals services is key to identify if patients have been deprived of the pass-on of the full price discounts offered by pharmaceutical companies, as required by CMED. Some courts have claimed that because CMED is responsible for the price regulation of drugs it is also the legitimate body to interpret Law N. 5.991 of 1973 and to prohibit hospitals from charging for drug dispensation. Hospitals that circumvent regulation to cash in patient surplus are getting a head start over the competition that complies.

5 Regulatory Solutions

Price competition among drugs and the value of generic drugs' price competition can be reaffirmed where discounts competition has grown strong and even replaced price competition.

One simple, but mistaken way to do so is to ban any sort of cash-in of the discount. That change can take place by modifying healthcare regulation to command that plans charge hospitals and clinics for the actual price they paid pharmaceutical companies. In fact, that regulation already exists: it is Resolution CMED N. 3 of 2009, as interpreted by Interpretative Orientation N. 5 of 2009, which has been contested in court by hospitals. Resolution CMED N. 3 of 2009 is not a good regulation though. Alone, its immediate consequence is to deprive hospitals from important economic incentives, which might lead to at least two undesirable outcomes.

First, although regulations like Resolution CMED N. 3 of 2009 make higher discounts lose their relative advantage in relation to lower prices, one can hardly claim that the regulation brings the proper incentives to buy cheaper generics drugs. Because compliance with this kind of regulation leads to the full pass-on of the price cap discount, hospitals lack the economic incentives to negotiate with the pharmaceutical companies.

Second, as hospitals no longer have the incentives to negotiate prices with the pharmaceutical companies, those pharmaceutical companies will fully cash in the surplus that

e Análises Clínicas no Estado de São Paulo (SINDHOSP) e outros); 5029410-19.2018.4.02.5101 (Sindicato dos Hospitais, Clínicas e Casas de Saúde do Município do Rio de Janeiro (SINDHRIO)); 1023105-76.2018.4.01.3400 (Sindicato dos Hospitais e Estabelecimentos de Serviços de Saúde da Baixada Fluminense (SINDHESB)); 1005566-63.2019.4.01.3400 (Sindicato dos Estabelecimentos de Serviços de Saúde do Sul de Santa Catarina (SINESSUL) e outros).

was once cashed in by the hospitals and the clinics, which does not help in any way to bring lower drug prices to end consumers.

If draconian rules like Resolution CMED N. 3 of 2009 are detrimental to overall price competition in drugs regulation, rules that incentivize discounts policy over price policy like Resolution ANS N. 241 of 2010 (as amended by Normative Resolution ANS N. 503 of 2022) can poison the generic drugs policy. As pointed out in this work (footnote 3), the ANS regulation and the 2010 report written by the working group that discussed hospital compensation (in which ANS also took part) have been interpreted as bringing a degree of flexibilization to CMED regulation and even accepting that hospitals and clinics can cash in price cap discounts offered by pharmaceutical companies.

Having that in mind, alternative strategies are key to (i) avoid the lack of interest by hospitals to negotiate with the pharmaceutical companies, (ii) provide hospitals with the incentives to prioritize better prices instead of higher discounts and (iii) force the pass-on of a fair share of the negotiated price difference to patients, all at the same time. The achievement of those three elements demands greater coordination between CMED, ANVISA and ANS, though.

To begin with, hospitals should inform ANS the actual price they paid for each medication and how much out of the full discount offered by pharmaceutical companies they passed on to the patients. Second, ANS and ANVISA should integrate their databases or at least the parts that are needed to enhance the performance and compliance of their own regulations. Third, the three sector regulatory bodies should make a greater effort to bring harmony to their rules, avoiding sending the market conflicting messages.

A complete improvement of the regulation should also encompass the empowerment of CMED with express authority to update the prices of drugs under certain circumstances. Access to SAMMED and to the ANS database should help identify situations where the gap between the competitive price and the regulatory price cap is too large and as a consequence CMED should act to decrease the payoff of price cap discounts vis-à-vis lower market prices. To put it different, the power to update prices according to the market value, to amend bad pricing decisions or to adjust prices as intellectual property protection expires should be able to neutralize major price distortions and could even reduce the appeal of price cap discounts.

That notwithstanding, healthcare plan regulation by ANS should also be improved to increase mechanisms that contribute to lower drug prices. First, regulation could create incentives that would allow the healthcare plans to use their bargain power to purchase and

offer drugs for lower prices to their customers. It could also create incentives that will lead healthcare plan corporations and consumer protection associations to flag price strategies that hospitals (and healthcare plans alike) negotiate and whose benefits they do not pass on. One way to achieve that would involve the design of a tripartite mechanism that distributes among hospitals, healthcare plans and patients the surplus arising from price negotiations. In order to work, all the involved parties – including the regulatory bodies – would be granted access to the price that hospitals paid for the drugs and how much has been passed on to the healthcare plans (and later on to the patients). As mentioned earlier, an integration between ANVISA's and ANS's databases would be key to make it possible.

Finally, hospitals and clinics alike could be sued for collective damages both for consumer protection and antitrust violations if the absence of the pass-on is consequence of abusive market dominance or abusive relationships with patients. If any sort of collusion is proved – horizontally or vertically, among hospitals/clinics and pharmaceutical companies – patients could also charge double damages pursuant to Law 14470 of 2020.

6 Final Remarks

This article shows how conflicting regulation across CMED, ANS and ANVISA, the lack of a dynamic pricing system that gives CMED the power to update the price caps of the drugs according to the competitive price and regulations that afford the prioritization of high price discounts over low drug prices have posed a threat to the generics public policy that is central to the sustainability of Brazil's Unified Health System.

By digging into (i) the data of several lawsuits, (ii) arrangements between ANS and the private sector representing both healthcare plans and the hospitals as well as into (iii) how CMED has behaved when confronted with the effect of the discounts policy over the generics pricing policy, we explain how resuming the attractiveness of the generics pricing policy in hospitals procurement shall encompass not only financial incentives that will encourage market players to look for the cheapest drug instead of the highest discount over high price caps, but also redesigning the regulation to narrow the gap between the regulatory price cap and the competitive price.

We conclude that the foundation of a better generics pricing policy relies on a triangular system: (i) the integration between the relevant databases of CMED, ANS and ANVISA, (ii) the empowerment of CMED to review and update the prices of drugs according

to their competitive value and (iii) offering hospitals the economic incentives to negotiate discounts with the pharmaceutical companies, but passing on a fair share of such discounts to the healthcare plans and to the end consumers.

Because stiff price competition affects the generic drugs' pricing policy and harms a cornerstone of Brazil's Unified Health System, market players could also be sued for collective damages both for consumer protection and antitrust violations if the absence of the pass-on is the consequence of either abusive market dominance or abusive relationships with consumers. Finally, if collusion is proved, the violator could also be charged with double damages pursuant to Law 14470 of 2020.

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