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Health Law: The Devil in the Tiers

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Introduction

Prescription-drug spending in the United States has soared in the last decade. A critical mechanism for restraining drug spending is the formulary system, which dictates whether, and the extent to which, a health plan will reimburse for a drug. Formularies, at the most basic level, are lists of medicines. Health plans divide today's formularies into tiers that determine how much patients pay out-of-pocket. When drugs are on low tiers, such as Tiers 1 and 2, patients pay less. When drugs are on high tiers, such as Tiers 4 and 5, patients pay more.

Formularies typically allocate drugs to tiers based on the price of the drug. Thus, lower-priced generic drugs are typically on the lower tiers, while higher-priced brand-name and "specialty" drugs are typically on higher tiers. In short, tiering encourages patients to choose less expensive generics over more expensive brands. A patient's copay is less, the cost to the healthcare system overall is less, and the market for cheaper drugs thrives. That is the concept of tiering, at least in theory.

This chapter examines whether tiers are doing their jobs. Based on a study of one million Medicare patients from 2010 to 2017, I find clear evidence of widespread improper tiering and wasted spending.[2] Specifically, cheaper generics are often placed on high tiers, sometimes even higher than their brand competitors, costing patients and the government billions of dollars. The solution is to require tiering based on list price, rather than net price. This simple, feasible solution will save costs, rationalize tiering, and disincentivize rebate gaming.

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[1] Excerpted and adapted from Robin Feldman, *The Devil in the Tiers*, 8 J.L. & BIOSCIENCES 1 (2021). The research summarized in this chapter was supported in part by a grant from the Laura and John Arnold Foundation.

[2] For further details on this study's methodology, see *id.* at 43–58.

Overview of Drug Pricing and Gaming

Price is a murky term in the prescription-drug world. A drug's actual, or net, price depends on rebates that are determined by complex calculations established in long-term contracts. Middle players called Pharmacy Benefit Managers (PBMs) establish the supply contracts and the terms of prices and rebates by negotiating with drug companies on behalf of health-insurance plans.[3] The health plans pay PBMs based on the size of the discount that the PBM can wrest from the drug company, sometimes even allowing the PBMs to pocket part of the spread.[4] This method—called spread pricing—should lead PBMs to negotiate more substantial discounts, which would, in turn, lower net prices.

Perverse incentives and strategic behaviors, however, have derailed the process. To increase the dollar flows to PBMs, drug companies raise list prices for drugs and then offer larger rebates. PBMs can then report a greater spread, thereby increasing their pay, even if the final price the health plan pays after rebate remains the same or even increases. This practice is akin to marking up the price of a jacket before a sale so that the sale price looks more appealing. The practice, however, creates upward pressure on drug prices, as drug companies offer—and PBMs demand—greater spreads. In other words, to keep the drug company's revenue the same, the net price must be the same. The only way to do that and increase the spread is to increase the starting price.

At the same time, the drug companies and PBMs assert that the rebates and net prices are trade secrets. Health plans, and even their auditors, are not allowed to know them.[5] Thus, for example, a health plan will know what it pays for a particular patient's heart medication at the moment of the purchase (the list price), but the plan will never know the true, net price because rebates on numerous purchases will be lumped together and delivered long after the patient leaves the pharmacy counter.

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[3] See Michael Hiltzik, *How "Price-Cutting" Middlemen are Making Crucial Drugs Vastly More Expensive*, LA TIMES (2017).

[4] *Id*.

[5] Robin Feldman & Charles Tait Graves, *Naked Price and Pharmaceutical Trade Secret Overreach*, 22 YALE J.L. & TECH. 61, 74 (2020).

This price gaming might be less of a problem if no one actually paid the higher list price. But many people do. Some health plans require that patients pay the full list price for a drug until reaching a deductible level or that patients pay a co-share amount calculated as a percentage of the list price.[6] Some patients lack health insurance or lack plans that cover medications. Even with full Medicare coverage, gaps can occur that leave patients paying a drug's full list price. And list prices are rising.

In exchange for the lucrative rebates that drive PBM profitability, drug manufacturers can demand that the PBM guarantee a certain volume flow from the health plan's patients by giving their drugs exclusive or preferred formulary placement. These volume rebates allow drug companies that hold substantial market power to secure favorable tier placement and prevent competitors from gaining ground.[7] In competition terms, this is a form of raising rivals' costs.[8]

The danger of volume rebates can be more pronounced in the context of large drug manufacturers offering a variety of drugs. A drug company offering multiple drugs can use its market dominance in one drug to protect its less-competitive drug. Brand drugs whose patents are expiring may hold monopoly positions that allow for this type of volume-rebate behavior.[9]

Anecdotal evidence has hinted at abuses in the formulary system, driven by the incentive structure in place and the type of strategic behaviors described above. One lawsuit alleged that health-insurance plans excluded a cheaper version of the arthritis

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[6] Norman Augustine, Guru Madhavan & Sharyl Nass, *Making Medicines Affordable: A National Imperative,* NAT'L ACAD. OF SCI., ENG'G, & MED. 76 (2018).

[7] For an extensive examination of the rebate system and its effects on competition, see ROBIN FELDMAN, DRUGS, MONEY, AND SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES (2019).

[8] *See* Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs To Achieve Power over Price*, 96 YALE L.J. 209 (1986); *see also* FELDMAN, *supra* note 7, at 38 (comparing the strategy of raising prices at the tail end of a monopoly period to "raising rivals' costs").

[9] *See* FELDMAN, *supra* note 7.

drug Remicade, following bundled-rebate deals from the brand.[10] Another alleged that a vaccine company significantly raised its prices for any consumers that did not buy a the full range of its bundled vaccines, in order to prevent customers from jumping ship to a recently introduced competitor.[11] Another alleged that a company used bundled rebates and exclusive formulary contracts to disadvantage competitors of the blockbuster dry-eye medication Restasis.[12]

Are similar manipulations occurring throughout the system, and can one see evidence of those manipulations in the drug-pricing tiers themselves? The study summarized in this chapter sets out to examine empirically whether evidence exists of widespread irrational tiering and problems created by that irrationality. The results confirm that the way drugs are currently being placed on formulary tiers is troubling, adversely affecting patients, and costing society.

Study Details and Results

To start, the price of brand drugs has risen at an astonishing pace, even after rebates, as Figure 1 below shows. Between 2006 and 2017, the average dosage-unit price for brand drugs, after rebates, increased 313%, from $38 to $157.[13] Brand *list* prices rose even more sharply. Between 2006 and 2017, the average dosage-unit list price for brand drugs rose from $42 to $221, a 426% increase. Both the amount and percentage increases for brand

[10] Compl. at 1, Pfizer, Inc. v. Johnson & Johnson, No. 17-4180 (E.D. Pa.).

[11] Class Action Compl. at 3, Castro v. Sanofi Pasteur Inc., No. 11-7178 (D.N.J.).

[12] Compl. at 6, 21–23, Shire U.S., Inc. v. Allergan, Inc., No. 17-7716 (D.N.J.) (alleging that according to one Medicare plan administrator, the new competitor could give its drug away for free and the numbers still wouldn't work).

[13] Drugs can be dispensed in different dosages, creating the need for a method of normalizing dosages and prices across different drugs. To solve this problem, the study uses a novel metric: the average dosage-unit price.

drugs contrast with the relatively stable $3–4 that plans pay for generics (for which rebates are generally not given).[14]

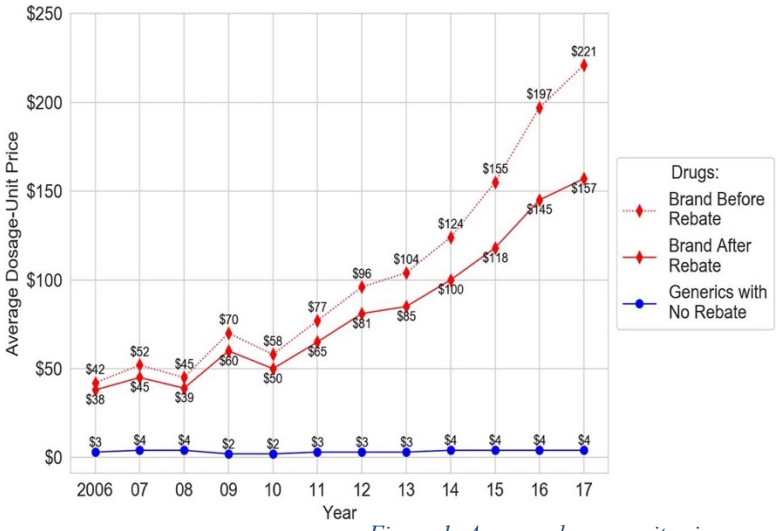

Figure 1: Average dosage-unit price

As noted above, tiering should reflect a drug's price, with cheaper generics placed on lower, less-expensive tiers and expensive brand drugs placed on higher, more-expensive tiers. But generics are increasingly losing out. In 2010, 96% of generics were placed on the two lower tiers (the most-favorable ones), but, by 2017, the percentage was 66%. The percentage of generics on the lowest tier decreased even more markedly, from 73% to 28%, even though the cost to health plans for generics remained stable. In contrast, the percentage of brand drugs on the lowest tier remained relatively constant throughout this time. Thus, generics specifically are being shifted away from the lowest tier.

Given that brand drugs are normally far more expensive than their generic competitors, a generic should be on a lower tier than a brand with the same active ingredient. Yet the study finds troubling evidence of "irrational tiering," in which a generic is

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[14] See CTRS. FOR MEDICARE & MEDICAID SERVS., 2011 MEDICARE TRUSTEES REPORT 183. Despite the price stability of generic drugs, out-of-pocket patient costs for generics rose 75% to roughly $7 per prescription across the study period. Thus, patient expenditures for generics are rising, while insurers pay roughly the same amount for generics over time.

placed on a tier equal to or higher than a brand with the same active ingredient.[15] In 2015, for example, 69% of generics experienced at least one improper placement. The trend is worsening over time. The percentage of generics with improper tiering has risen from 47% in 2010 to 74% in 2017. The rising incidence of irrational tiering corresponds with a drastic shrinking of the percentage of generic drugs in the first tier and with a sharp rise in the percentage of generic drugs in higher tiers.

To estimate the wasted cost of irrational tiering, the study calculated the out-of-pocket amounts that patients actually paid for individual drug purchases, combined with any amount that the federal government paid for that purchase through its Low-Income Subsidy Program, and then compared that total with the amounts that patients and the federal government would have paid if generics irrationally tiered had instead been tiered one level lower.[16] The findings are staggering. In 2017 alone the amount of wasted spending was $4.17 billion, an 83-fold increase over 2010. The total wasted spending across the entire 2010–2017 study period amounts to $13.25 billion.

Solutions

Tiering today is based on the net price, which is the bottom-line cost to the insurer. But the net price is subject to rebate gaming. If tiers were based on *list* price, drug companies that raised prices to give space for rebates and other payments to PBMs would find that the strategy backfires. The high list price would drive the company's product to a higher tier, making it unattractive in comparison to cheaper substitutes.

List-price tiering would also be more transparent. PBMs have aggressively claimed that net-pricing information constitutes a trade secret. List prices have no claim to secrecy. Medicare regulations already require drug companies to report the list price, including providing penalties for failure to report.

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[15] For information on the study's parameters, see Feldman, *supra* note 1, at 19–20.

[16] Rationalizing tiering by lowering the generic by just one level is highly conservative; accurate tier placement would be far lower in cases of large price differential.

A regulatory path for list-price tiering exists today. The Center for Medicare and Medicaid Services (CMS) could choose to require list-price tiering, in accordance with its mandate of providing high-quality, cost-effective drug benefits. Similarly, given that CMS already reviews and provides guidance on formularies, Congress could easily grant any additional authority necessary to further regulate formularies and require list-price tiering. Given that instituting such a broad change for the private, health-insurance industry could be practically challenging and politically daunting,[17] moving tiering to list prices could begin with the Medicare system, with the potential to create ripple effects in the private-insurance market.[18]

Conclusion

No single solution can possibly solve all problems within the formulary system, let alone with pharmaceutical pricing. This study and its recommendations presuppose a smoothly functioning generics market. If other strategic behaviors block or hinder that market,[19] all the formulary reform in the world will not help. Nevertheless, abuses of the formulary system have cost patients and the government over $13 billion from 2010–2017, with the problem growing across time. Tiering can play a critical role in driving patient behavior, but the devil is in the tiers. By reforming legislative or regulatory rules to require that tiers reflect list price, government officials can restore proper incentives in the

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[17] *See* David Brady & Daniel Kessler, *Why is Health Reform so Difficult?*, 35 J. HEALTH POL., POL'Y & L. 161 (2010).

[18] For factors that potentially limit the ability to project the study's findings onto the private-insurance market, see Feldman, *supra*, note 1, at 28–30.

[19] *See* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 OXFORD J. L. & BIOSCI. 590 (2018) (examining extent of patent evergreening and its anticompetitive effects); Robin Feldman et al., *Empirical Evidence of Drug Pricing Games—A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39 (2017) (exploring abuse of citizen petition process by drug companies to delay approval of generic competitors); Robin Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHICAGO-KENT J. INTELL. PROP. 101 (investigating use of pay-for-delay tactics to stifle competition).

drug-coverage system, with the happy side effect of discouraging anticompetitive rebate and kickback schemes.

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