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How Congress Can Make Drug Pricing More Rational

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The public reproach over the price of Mylan's lifesaving drug EpiPen is the latest imbroglio in a much broader debate over drug costs. At issue is the rising list price on drugs. But as <u>Mylan</u> argued, these high reported prices often bear little relation to the real price actually paid, after rebates and discounts, by most health plans.

The question is how we can bring more prudence to this complex system, in which drug discounts don't flow evenly to the patients who need access to these medicines.

Mylan pointed to a long sequence of drug supply middlemen who get a series of rebates, mostly as economic inducements for helping drug makers sell their medicines. To fund these rebates, drug makers push up the list price of their pills, only to furtively pay much of the money back to pharmacy benefit managers later.

This byzantine model for selling drugs aids both parties—the drug makers who use the rebates to buy access on restrictive drug formularies, and the pharmacy benefit managers that take a cut from these rebates to improve their profit margins.

But the entire scheme isn't a concoction of business efficiency. It's the outcome of a <u>two-decade</u> <u>old legal dispute</u> that forced drug makers to try and conceal just how much they discounted off the medicines that they were selling to health plans.

Addressing the precedent set by that court ruling, and the intricate system it created, could provide policy makers with a simple way to improve the transparency, competitiveness and affordability of how drugs are priced and sold.

Principal among the drug supply middlemen are the pharmacy benefit managers, which Mylan blamed for its price increases. PBMs add a lot of efficiency to the way drugs are sold. By

negotiating on behalf of millions of consumers, PBM's are able to extract large discounts and use formularies to help health plans control spending.

But the need to rebate money to the PBMs, in order to drive formulary access, is also a principal reason that drug makers raise the list price on their drugs. As evidence, <u>Mylan offered</u> the fact that its net revenue on each EpiPen is well below its list price, and has actually fallen even as Mylan has taken big price increases.

The rebates benefit both sides of these transactions. The drug makers use bigger rebates to buy preferred access on the increasingly narrow formulary lists that the PBMs market to their clients (principally insurance companies and self-insured businesses). At the same time, PBMs profit by taking a cut of the rebates, before they kick most of the money back to the employers or insurers that are paying the bills.

But this doesn't explain why the drug makers offer rebates that are forfeited well after the drugs are purchased and paid for, rather than advance discounts that are offered when these transactions are first placed. After all, money earned today (from a discount) is worth more than money earned tomorrow (from a rebate). So why has much of the discounting come in the form of these back-ended payments?

A lot of it has to do with a legal <u>dispute from the late 1990s</u>, where pharmacies contended that-when it came to offering drug discounts--the pharmaceutical companies arbitrarily discriminated between the pharmacies and the HMOs. The suit alleged that the drug makers violated the Sherman Antitrust Act by conspiring to charge independent and chain pharmacies more money for brand-name prescription drugs than they charged HMOs or hospitals.

These lawsuits, which were first filed in 1993, were eventually consolidated into one class action. The suits generally alleged that a dual system of drug pricing had improperly arisen in the U.S. during the first half of the 1990s. There was a discounted pricing system that drug makers offered to big HMOs, while much higher prices were offered to drugstores and pharmacy chains. At issue was whether this two-tiered pricing system stemmed from normal market forces, as the drug industry argued, or from a price-fixing conspiracy, as the plaintiffs maintained.

In a 1996 opinion, a federal court largely agreed with the pharmacies, prompting the drug makers to settle the lawsuit. What happened next is how we developed the system in place today. To work around the litigation, and the settlement they struck with the pharmacies, drug makers came up with a rebate scheme rather than offering discounts up front. The new scheme was built on two components.

First, the rebates had to be linked to some back-ended measure of market share as a way to avoid looking like a discount. Second, the measure of market share had to use a denominator that the retail pharmacies couldn't prove independently.

So the drug makers agreed to pay rebates of a certain percentage to participants who could demonstrate that a certain amount of the total prescriptions that were consumed by patients were covered under a specific insurance plan. If it sounds complicated, this was purposeful. Through

this convoluted scheme, the same terms could be "offered" to the retail pharmacies. But the drug makers knew that the retailers couldn't possibly fulfill the burden of proof needed to qualify for the rebate.

Since that legal settlement in the late 1990s, the existence of rebates rather than discounts took hold, and the linkage between rebates and a drug's market share remained tight. The practice has been to hold back some portion of the rebate until the market share calculation can be evidenced. This post hoc nature of the rebates is crafted as a work-around to the litigation. For obvious reasons, the drug makers don't want to write contracts with the insurers that the retailers could also demand.

The way this system is designed, it's inevitable that there would be a growing disconnect between the publicized "list" price of a drug, and the real price that's paid by large purchasers. The political class is using these anecdotes of excessive list pricing to further a legislative push for enactment of drug price controls. But the list prices that are being objectified are disconnected from the real costs, despite the best attempts of drug industry critics to blur these economic distinctions.

This doesn't mean some patients don't get stuck with the high list prices. It's usually the underinsured or uninsured that can end up paying the full amount. It's precisely the folks who can least afford these costs. But instead of seeking to leverage the confusion between perceived and actual costs, and pretend that the list price reflects the average price, Congress can act instead to end the nonsensical pricing.

Congress can enact legislation that would address the judicial precedent that gave rise to this purposely-intricate system of rebates. If insurers could demand up-front discounts, rather than back-ended rebates, and drug makers were free to offer them; then more of the markdown would come in the form of lower opening prices.

Of course, it's probably going to be the case that most of the PBMs and drug companies don't want to end these rebating schemes. Such an outcome would also cut their reported gross revenue, even if they never realize the bulk of that revenue as net income because they have to pass it on to other intermediaries.

Government payers like Medicaid would also resist such a change. The government uses the rebates as a way to re-allocate healthcare dollars to other projects, while being able to still claim that their reported pharmacy budget is rising by ridiculous amounts. Right now, average rebates for Medicaid are about 65% and growing.

The convoluted arrangement by which drugs are priced and sold arose accidentally as a result of litigation. But now that this inept system is firmly entrenched, bringing rationality to the selling model is going to disrupt inter-reliant business practices. As much as the drug makers complain about the rebating scheme, they've grown as dependent on its subterfuge, opacity and inequity as everyone else in the system.

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