A Drug Rebate's Tale: How a Class Action Lawsuit in the 90s Shaped Drug Pricing

Do you ever wonder why it is so hard to know what a prescription drug actually costs? How did we get a system where prices are obscured, even from insurers, and contracts prevent pharmacists from telling patients when they are paying more than they should be? How did the pharmaceutical industry wind up in a world of rebates and complicated contracts with pharmacy benefit managers that result in a lack of transparency for everyone?

Setting the Stage: The Lawsuits that Laid the Groundwork

To understand how we got here, we must journey back over two decades. The year was 1996 and fifteen major drug manufacturers have agreed to pay $408 million to settle a class action lawsuit.[1] This agreement settled multiple lawsuits filed in the early 1990's that eventually consolidated into one class-action lawsuit in which pharmacies alleged that 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 to managed care groups, including Health Maintenance Organizations (HMOs). Because HMOs often tightly restrict which drugs are covered on their drug formulary, they can strongly influence the prescribing behavior of physicians. As a result, manufacturers offered significant discounts to HMOs, but not to pharmacies, because they believed pharmacies lacked such a strong influence on what medicines were prescribed. Retail pharmacies and pharmacy chains, however, claimed that

the two-tier system of pricing was a result of collusion between drug manufacturers rather than market forces and kept prices artificially high for pharmacies. They alleged that "virtually all of the leading manufacturers and wholesalers of brand name prescription drugs… collusively created and maintained a dual pricing system that rais[ed]… the prices for brand name prescription drugs."[2]

In denying the manufacturers' request for dismissal, Judge Charles P. Kocoras of Federal District Court in Chicago said that the drug manufacturers' "opportunity to conspire is unquestionable. The record is replete with evidence of seminars and trade association meetings which virtually every defendant attended at one time or another and a coordinated exchange of pricing and other competitive information shared among the manufacturers."[3] As a result of early rulings against them, drug manufacturers agreed to substantial settlements with the pharmacies and agreed to avoid any two-tier pricing setup in the future by offering similar pricing contracts to all purchasers.

The Rise of the Rebates

Drug manufacturers still wanted to offer discounts dependent on the volume of drugs sold so that HMOs and other payers would put their drug on a preferred tier of a formulary. As a result, a manufacturer would offer a rebate for *any* purchaser, regardless of whether they were a pharmacy or an insurer, who could demonstrate that a certain fraction of the drugs used in a therapeutic class were for a particular drug from that manufacturer. For example, if a purchaser demonstrated that 40% of all prescription drugs dispensed in a therapeutic class were for a specific drug, the manufacturer of that drug would offer an additional 10% discount to that payer.[4] Manufacturers, however, often based these rebates on complicated formulas and structured the agreements in a way

that pharmacies were unable to provide the evidence to prove qualification for the rebates.[5] Furthermore, since the percentage of the market share that a drug represents could only be calculated retrospectively, the industry moved to a system of rebates that were typically paid substantially after the drug is dispensed at the pharmacy. The legal settlements reached in the late 1990s ensured that post hoc rebates, and not upfront discounts, became commonplace in the pharmaceutical market. The rebate system means that *no one* knows the actual price of the drug at the time it is sold by the pharmacy. The list price became an artificial, maximum price.

Modern Day Dystopia: Rebates Lead to Increased Drug Costs

In the years since these settlements, the pharmaceutical industry evolved into an intricate, complicated system of rebates and opaque pricing. Drug makers increase the list prices of drugs so that they can offer bigger rebates to buy preferred access on the increasingly narrow formulary lists that the pharmacy benefit managers (PBMs) market to their insurer clients. At the same time, PBMs profit from increasing prices because they often taking a cut of the rebates, before passing the bulk of the rebate back to the final payer, typically the insurer or employer. This system has led to a growing gross-to-net bubble – list prices increase, but revenues to drug manufacturers decrease as manufacturers pay larger rebates to PBMs and insurers. As discussed previously on the Source, this system leads to a lack of competition for drugs in the same therapeutic class and disproportionately hurts sick patients, the uninsured, and those within the Medicare Part D coverage gap.

A Brave New World: Discounts That Replace Rebates

Dr. Scott Gottlieb, the commissioner of the Food and Drug Administration (FDA), and many others recognize the inequity of the rebate system and how it keeps drug prices high. In 2016, as a Resident Fellow at the American Enterprise Institute, Scott Gottlieb testified before the Senate Committee on Health, Education, Labor, and Pensions (HELP). In his written testimony, Gottlieb asked if Congress could disrupt this rebate system by making "it legal for drug makers to engage in price discrimination based on purchaser, offering discounts to one channel and not to another, so long as the drug makers were not conspiring to offer similar discounts?"[6] He goes on to assert that "[i]f drug makers could offer discounts, purchasers would start demanding them. A discount would potentially be far more equitable, transparent, and pro-competitive than a rebate – especially where the rebate does not flow evenly to all consumers. Increasingly, it's consumers who are underinsured or uninsured that are stuck paying the full list price at the pharmacy counter."[7]

Discounts would help pop the gross-to-net bubble, thereby decreasing patient cost-sharing. Adam Fein, author of the Drug Channels blog and expert on the drug distribution system, predicts that a system of discounts rather than rebates would mean that "[r]evenues at wholesalers, pharmacies, and PBMs would collapse. Profits would become more visible."[8] With more transparent pricing, competition in the pharmaceutical market would increase. Patients and physicians would finally be able to weigh the cost of a treatment with its benefit.

The Promised Land: A Pricing System that Measures Value Rather Than Price

The ability of patients and doctors to make a meaningful cost-benefit analysis about treatments would increase the efficiency of the market. When drug prices do not reflect

value, the high price tags simply generate profit for pharmaceutical companies and increase healthcare costs for all Americans. Excessively priced drugs with minimal therapeutic benefit exploit patients who are willing to pay astronomical amounts for drugs that treat terminal diseases with no alternative effective treatments. When drug prices are transparent and reflect the relative value to patients, however, transformative treatments can demand high prices, while drugs that have many therapeutic equivalents or offer little clinical benefit would face stiff competition. As Scott Gottlieb asserted in his 2016 HELP testimony, "[w]e need to allow innovative drugs that offer meaningful advances in medical care to be priced in a market system based on the benefit that they offer… We don't want to undermine the model for investment and innovation that makes these advances possible and has given us the most vibrant market for the research and development of biotech and drug products in the world."[9] All members of society benefit when the pharmaceutical industry invests heavily in research and development and releases innovative products that revolutionize treatments for debilitating diseases.

In addition, allowing pharmaceutical manufacturers to offer discounts rather than rebates to health plans and PBMs that create formularies could meaningfully increase the competition between drugs and alternative treatment options. In many diseases, pharmaceuticals are the least-costly treatment option. Increasing the number of statin prescriptions for those patients who need them, for example, decreases the number of heart attacks and strokes and decreases overall spending on healthcare. In 2012, for example, the Congressional Budget Office calculated that a 1% increase in the number of prescriptions filled by Medicare beneficiaries yields a 0.2% decrease in Medicare's *total* medical spending.[10] One study found that every dollar spent on drugs for diabetes saves an estimated $7.10 on other care.[11] With the current system of rebates and obscured pricing, providers

and insurers can find it difficult to do a cost-benefit analysis for prescription drug coverage. When payers and patients know the actual price of a medication, they can make decisions that improve outcomes and save money. A more equitable system of drug pricing that include discounts rather than rebates calculated in an obscure manner would decrease patient cost-sharing for those who can least afford it and increase competition in the pharmaceutical industry to decrease drug prices and overall health spending for all Americans.

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[1] Milt Freudenheim. "Drug Makers Settle Suit on Price Fixing." *New York Times*. February 10, 1996. Available at: http://www.nytimes.com/1996/02/10/business/drug-makers-settle-suit-on-price-fixing.html.

[2] In re Brand Name Prescription Drugs Antitrust Litigation, United States Court of Appeals, Seventh Circuit August 15, 1997 123 F.3d 599.

[3] In re Brand Name Prescription Drugs Antitrust Litig., No. 94 C 897, 1996 WL 167350, at *10 (N.D. Ill. Apr. 4, 1996), opinion modified on reconsideration, No. 94 C 897, 1996 WL 351178 (N.D. Ill. June 24, 1996), and rev'd, 123 F.3d 599 (7th Cir. 1997).

[4] Ernst R. Berndt and Joseph P. Newhouse. "Pricing and Reimbursement in U.S. Pharmaceutical Markets" NBER Working Paper No. 16297. Issued in August 2010. Available at: http://www.nber.org/papers/w16297.

[5] Scott Gottlieb. "EpiPen Price Increases: How Regulatory Barriers Inhibit Pharmaceutical Competition." *Statement before the Senate Committee on Health, Education, Labor, and Pensions; Subcommittee on Children and Families*. October 7,

2016. Available at: http://www.aei.org/wp-content/uploads/2016/10/HELP-Written-Testimony-FINAL-10-7-16.pdf.

[6] *Ibid.*

[7] *Ibid.*

[8] Adam J. Fein. "Scott Gottlieb's Radical Idea for Disrupting U.S. Drug Channels: Implications for PBMs, Wholesalers, and Pharmacies." *Drug Channels Blog.* March 14, 2017. http://www.drugchannels.net/2017/03/scott-gottliebs-radical-idea-for.html.

[9] Gottlieb testimony p. 4.

[10] Offsetting effects of prescription drug use on Medicare's spending for medical services. *Congressional Budget Office Report*, November 2012. Retrieved at: http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf.

[11] Sokol, M. C., K. A. McGuigan, R. R. Verbrugge, and R. S. Epstein. "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost." *Med Care* 43, no. 6 (Jun 2005): 521-30. Summary accessed at: http://www.pfizer.com/sites/default/files/health/VOM_MedicalCosts4.pdf.