

**Federal Trade Commission Workshop on
Understanding Competition in Prescription Drug Markets:
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The prescription drug market is unique and complex, and it is appropriate to carefully examine all elements of that market that may be contributing to the striking extent of inflation in prices for existing prescription drugs, and launch prices for new drugs that continue to spiral upward. It is also appropriate to focus in part on questions of agency and the possible role of the various kinds of intermediaries in the supply chain in the total economics of the market, as many observers have recently done¹.

It seems obvious to observe that intellectual property rules granting monopolies lead to rent seeking behavior by drug manufacturers. This market dysfunction is a natural but perverse incentive for large companies, and is compounded by the dampening of cost sensitivity resulting from third party payment now covering the vast majority of prescription drug costs. Dysfunction also arises from the fact that prescribers do not usually bear the risk for the cost of drugs they select for patients. This can be mitigated to some extent through sound clinical management, including the use of formularies to choose among similar and similarly effective drugs, and leveraging those activities to negotiate lower prices for drugs.

As the largest integrated health care delivery system in the United States, we provide both coverage and care to 11.8 million people in 8 states and the District of Columbia. Within that footprint, we maintain a highly integrated, internalized pharmacy system, including 395 outpatient and 38 inpatient pharmacies, 90 clinic administered drug sites (including oncology, outpatient infusion and specialty drug sites), and 27 call center and central fill facilities, staffed by over 15,500 pharmacists and staff. In 2016, Kaiser Permanente dispensed 81.5 million outpatient prescriptions, administered 44 million inpatient doses of prescription drugs, and administered 10.6 million doses through our outpatient clinics. Kaiser Permanente's total drug spend is approaching \$8 billion annually.

Kaiser Permanente provides a somewhat unique window into the demand side of the market where potential problems of agency are less acute. While Kaiser Permanente is not a group purchasing organization (GPO), or a pharmacy benefit management company (PBM), it does use the same tools as GPOs and PBMs to drive pharmaceutical suppliers to lower the price of prescription drugs. We do contract with both PBMs and GPOs to support our supply chain needs.

¹ For example, see comments on the relationship between consolidation and rebate arrangements negotiated by PBMs in Scott Morton, Fiona and Boller, Lysle T., "Enabling Competition in Prescription Drug Markets," Brookings Hutchins Center Working Paper #30, May 2017, pp. 20-23.

We also find that PBMs can process external claims and manage a retail pharmacy network for the relatively small number of prescriptions we cover when filled outside of our delivery system far more efficiently than we can internally. Our internal drug purchasing staff manages most of our drug price negotiations with manufacturers. Our relationship with GPOs is largely limited to medical supplies and devices, and supplementing our own internal purchasing function, and we chiefly rely on them to help us cover the full range of products we require rather than managing through internal staff.

Drug selection within our organization is centered around a Permanente physician-led, Kaiser pharmacist supported Pharmacy and Therapeutics process, where up-to-date clinical information is brought before physician experts to help develop a formulary of preferred drugs for those practitioners to manage the care of our patient population. Because of the high degree of confidence in the quality and integrity of this process, prescribing by physicians within Kaiser Permanente is highly consistent with formulary recommendations. For this reason, our purchasing staff can readily demonstrate to drug manufacturers that preferred drugs can capture a high degree of potential market share within Kaiser Permanente.

All of this work is done with an intent to enable our clinicians to deliver affordable, high quality care to our members and patients. Our goal is to compete successfully as an integrated delivery system against other health plans on both price and quality to provide the full range of health care services, including prescription drugs. Because prescription drug benefits can be carved out, we must demonstrate both efficiency and quality to our customers specifically in that domain. Achieving a competitive price requires seeking the lowest possible net cost of prescription drugs.

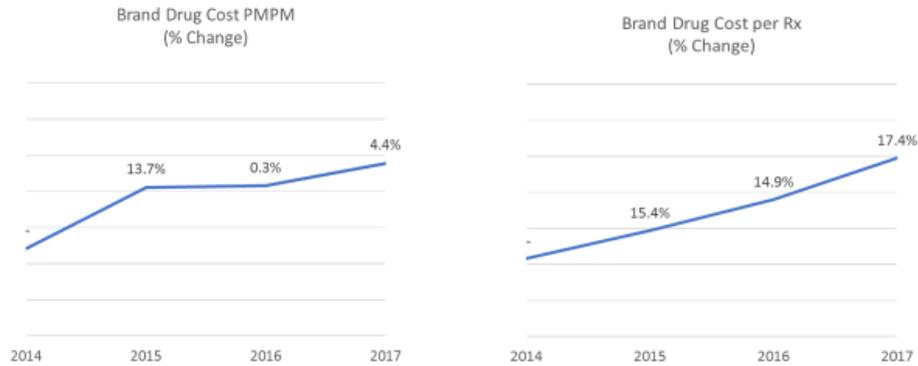
What we find is that even an organization with underlying economics to seek the lowest possible net cost of prescription drugs, and that maintains an optimally aligned delivery system that enables it to provide high quality, comprehensive drug coverage, the continuously escalating prices charged for prescription drugs continue to frustrate those efforts.

While the prescription drug market is complex, and the fragmented supply chain is a significant contributor to that complexity, even well organized, aligned purchasers like Kaiser Permanente continue to suffer inexplicably escalating drug prices. In our experience, most of the problems flow from manufacturer pricing decisions, whether it is introductory prices that are too high, shadow pricing against those excessive introductory prices, or price increases for no reason at all.

A few data points might be helpful:

- The trend we see in brand name drugs reflects much of the rest of the market, with the only moderation coming last year based on the first true price moderation for Hep-C drugs.

Outpatient Brand Drug Cost Trend



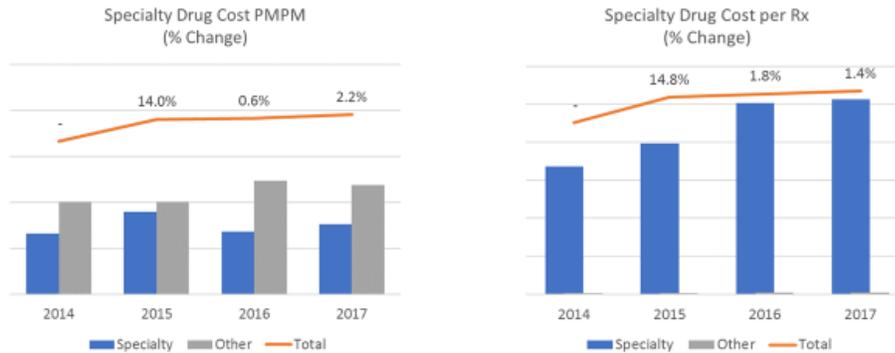
- Outpatient drug spend on brand medications has increased steadily over the last four years, averaging 16% in annual growth on a cost per prescription (RX) basis. On a PMPM basis, brand drug cost growth plateaus in 2016 due largely to lower hepatitis C utilization.

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- Specialty drug pricing is a particular concern – they account for 1% of our total outpatient prescriptions, but 39% of our outpatient drug spend.

Outpatient Specialty Drug Cost Trend



- Specialty drug is defined as cost of \$600 or more for a 30 day prescription. As of YTD Sep 2017, specialty drugs represented 39% of the total outpatient drug spend but only 1% of the total outpatient prescription volume.
- Specialty drug cost on a PMPM basis has increased steadily with the exception of 2016, driven by the decline in hepatitis C utilization. Specialty drug cost on a cost per prescription basis has increased steadily, slowing in 2017 as a result of lower hepatitis C spend.

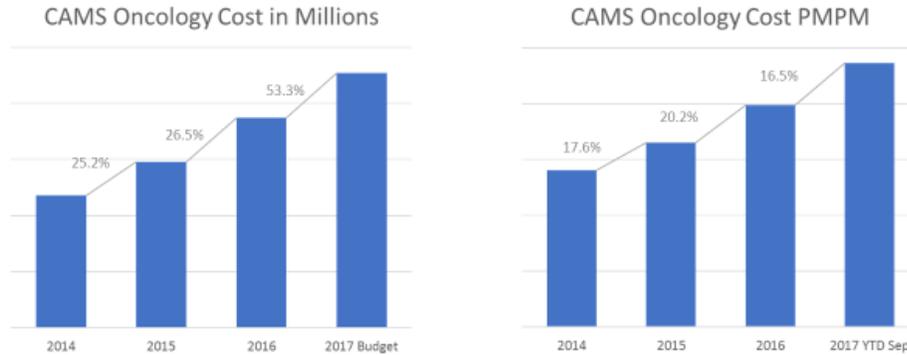
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Celgene has raised the price of Revlimid three times this year alone, for a cumulative increase – on the same drug – of 19.8%. The company has also raised the price of Pomalyst twice for a cumulative annual increase of 17.7%

- Clinic Administered drugs are frequently left out of price increase reports, often to disguise their enormous impact. Increases for clinic-administered oncology drugs alone have a major budgetary impact.

Clinic Administered Medications (CAMS) for Oncology



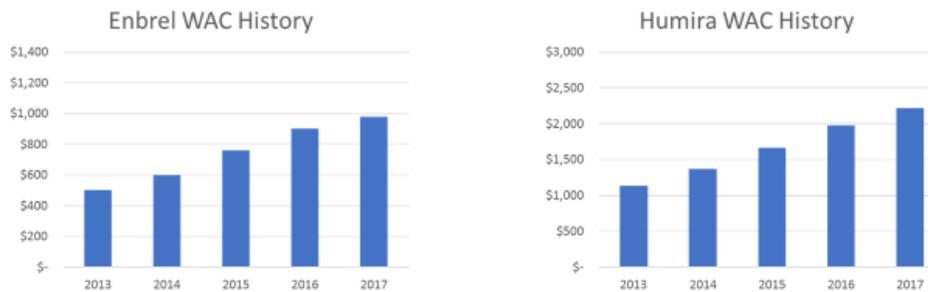
- Clinic pharmacy drug spend for oncology have increased by double digit percentages annually on a dollar and dollar PMPM basis.
- The increase in spend is driven by increases in both utilization from expanded FDA indication approvals and by unit cost increases.

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- The Compounded Average Growth Rate for two drugs, Enbrel and Humira, increased over the same four year period by nearly identical rates: 14.4% and 14.2%. These two drugs, alone account for \$18.8 billion in sales in 2016, have respective wholesale acquisition costs within \$8 of one another: \$41,460 and \$41,468 for an annual course of therapy.

Wholesale Acquisition Cost (WAC) Example



- Significant growth has been experienced for Enbrel and Humira demonstrate the increasing cost to treat patients with rheumatoid arthritis. This is one example of the rising cost of specialty drugs.
- Enbrel WAC increased by a compounded average growth rate or CAGR of 14.2% between 2013 to 2017
 - Price changes include various dosage forms of the injection and Sureclick® injection.
- Humira WAC increased by a CAGR of 14.4% between the same time period
 - Price changes include various dosage forms of the pen injection and kit injection.

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It is also worth examining how the new hepatitis C drugs entered the market.

- Sovaldi came to market at twice what its developer projected, largely because Gilead paid twice as much for its developer, and it was more willing than others to face the controversy of a surprisingly high launch price
- The second in class launched at roughly the same price
- This pricing directly caused public programs to have to ration access to the drug, missing the opportunity to view this as a public health opportunity
- It was only the notable and rare lower launch price of Zepatier that led to meaningful reduction of the price into a more manageable range.

While there may be some truth to the claims that PBMs, GPOs or others prefer higher list prices to generate larger rebates, the manufacturers are the only ones with the power in our system to set the bar for any future negotiations, and they do so to create incentives within the market to achieve their own goals of increasing revenues. If even well organized, aligned purchasers like Kaiser Permanente continue to endure these inexplicably escalating drug prices, it is hard to see any market force that can counter the market-defying perversity of pharmaceutical pricing. The fact is that everything in this market hangs off the list price set unilaterally by the manufacturer: introductory prices that are unreasonably high, large price hikes for small changes in formulation or dosing; price increases for drugs in short supply; or price increases for no reason at all. States from California to Vermont are now passing legislation to require some level of transparency and justification for drug prices. A similar bill has been introduced by Senators John McCain and Tammy Baldwin. We strongly support this approach, taking the first steps to hold the pharmaceutical industry accountable for their pricing as others in the health care industry are.

What factors do we think have led us to a place where the market is designed to free the hand of manufacturers to raise prices and punish or disable negotiation of lower prices?

The Anticompetitive Design of the Medicaid Rebate Program

It is ironic that the rebate system is now being called into question as “the problem” underlying high drug prices. The rebate system was developed in the 1980s to enable drug manufacturers to offer price concessions to the parties that had the capacity to influence drug selection but did not purchase drugs directly, thereby responding to an appropriate competitive force. (Organizations like KP were always able to negotiate discounts if a drug faced potential competition.)

That competitive force was significantly undermined in 1990 when Congress enacted the Medicaid drug rebate program as a part of budget reconciliation, using a most favored nation provision known as “best price.” By granting Medicaid programs a privileged status among payers for brand name drugs, manufacturers were placed into a system where they knew their competitors would suffer severe financial penalties for competing aggressively on price. This caused deep discounts to evaporate overnight. The 1993 extension of best price to public hospitals and other organizations serving significant populations of low income individuals exacerbated this effect. That system is largely intact today.

Changing how rebates are calculated – by removing the most favored nation element of the formula and replacing it with a guaranteed percentage, protecting Medicaid and allowing it and others to continue to negotiate lower prices – would bring an important competitive force back into the marketplace.

Formulary Inclusion Mandates

Early in the 2000s, and culminating in the enactment of the Medicare Modernization Act and Part D, we also saw very intrusive formulary regulation emerge in Congress and the state legislatures. By forcing more drugs onto formularies that clinical managers believed necessary – multiple drugs in each therapeutic class in Part D, with CMS requiring all drugs in six protective classes be included in all formularies – manufacturers saw less competitive pressure than would naturally occur. Fortunately, Congress exempted Part D plans from the Medicaid best price rule, and so some price concessions have been able to be negotiated.

Formularies remain a critical tool in managing both drug costs and quality care for patients. This is particularly true for Kaiser Permanente, and laws or practices that encroach on the ability to use this tool lead to a less competitive market for drugs.

Orphan Drug Abuses

The Orphan Drug Act was intended to create incentives to manufacturers to develop treatments for rare diseases. Today, manufacturers seek orphan indications to apply to existing drugs, turning this incentive on its head and allowing massive price increases. The fact that Humira, the drug with the highest worldwide sales by dollar volume, can be granted orphan status is particularly illustrative of the perverse results of this well-intentioned legislation.

REMS Abuses

One of the greatest barriers for organizations like Kaiser Permanente seeking to effectively manage high priced specialty drugs is the application of gratuitous and overreaching Risk Evaluation and Mitigation Strategies (REMS) by manufacturers. As an integrated healthcare delivery model, Kaiser Permanente presents a reasonable model for determining the workload impact of REMS upon healthcare delivery systems and the components of care delivery – prescribers, pharmacies, nursing care, laboratory, insurer, and other healthcare services. Within Kaiser Permanente, the additional workload associated with REMS is evaluated retrospectively or concurrently for drugs with REMS already initiated, as well as prospectively for REMS currently being implemented.

When a manufacturer can control the downstream supply chain by requiring that all providers access a drug through a select specialty pharmacy, the provider organizations cannot maintain the necessary oversight to manage the patient, or control costs. Once a prescription must be

dispensed outside of our system, we frequently do not receive the routine monitoring information that is essential to our fully integrated electronic health record system.

Drugs distributed in this manner tend to be much more expensive, usually with charges reflecting the full Wholesale Acquisition Cost (WAC) plus an additional charge.

In December 2009, KP filed a Citizen's Petition with the FDA discussing in detail the problem with manufacturers imposing requirements that limit safe, effective and efficient distribution and access systems. We have not received a response. While we appreciate the burdens faced by FDA staff, lax oversight of manufacturer REMS abuses is driving prices higher. We would encourage the FTC to step in whenever REMS are having deleterious effects on the market.

Drug Coupons, Charitable Programs and other Schemes

One of the great benefits to consumers and the drug industry is the broad availability of health insurance to cover the majority of costs resulting from high prices charged by drug manufacturers. When differential cost sharing, designed to encourage the use of the most appropriate and least costly alternative drug, is undermined by any scheme to eliminate the higher cost sharing, it should be understood and treated as an abuse. So-called "charitable" programs by manufacturers to help cover cost sharing are in fact schemes to support higher prices within an insurance system. There's a good reason that they are prohibited in public programs. They should be illegal in any third-party coverage situation.

Generic Shortages

One thing all purchasers, including GPOs, PBMs and integrated systems have in common, is a strong interest in a healthy and sustainable generic drug industry. We believe that the consolidation in that industry runs the risk of eliminating manufacturing capacity and market participation, resulting in significant drug shortages.

For example, in the FTC's staff report from earlier this year examining FTC merger remedies², table 8 on p. 31 shows that for mergers between 2006-12, complex generic products where manufacturing transfer was required had a 36% failure rate for reaching the market. The report does not examine possible reasons for this, but the magnitude of the failures is cause for further inquiry. At the very least, the acquirer should be required to provide a rationale for generics that do not make it to market.

This also creates the kind of opportunities for abuse we have seen in the past several years with malevolent actors acquiring old, single source generics and pricing them in line with today's excessively priced new specialty drugs.

² https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf

It is very important that government agencies, like the FTC, take a long view on what is happening in the generic market, and work to ensure that patients will continue to have access to these critical drugs at an affordable cost.