Has the Problem of Increasing Drug Prices Really Passed?

The rate of increase in spending on pharmaceuticals is *declining*, according to a <u>Quintiles-IMS Health report</u> from May of 2017.[1] In 2016, the rate of increase in spending on pharmaceuticals was only 4.8% on a net basis (i.e. including rebates and discounts) – less than half that in 2014 and 2015, although it remains much higher than inflation. Express Scripts, one of the largest Pharmacy Benefit Managers (PBMs) in the U.S., <u>reports</u> that in their employer-based plans, perperson spending on prescription drugs increased just 3.8%, much lower than previous years.[2] Furthermore, the Quintiles-IMS report finds that net per capita drug spending has been relatively unchanged over the past decade. Specifically, they find that per capita spending on pharmaceuticals has increased an average of only 1.1% per year, from \$805 per person in 2006 to \$895 in 2016.[3]

Assuming those reports correctly reflect what is happening in the industry (more on that in a minute), do the results imply that the period of rising prescription drug costs has passed? Is all the media and legislative focus on reining in drug prices misplaced?

Not so fast... A closer look at the data reveals two troubling details. First, the increase in invoice prices pushes more of the costs on to patients and small business without substantial market power. Second, generic drug prices have decreased at the same time that manufacturers released expensive specialty drugs. In the past few years, these factors have balanced out because the specialty drugs were prescribed to few patients, but as they become more widely used, drug expenditures will again escalate.

Increased Invoice Prices relative to Net Prices Hurts Those

Without Market Power

Nearly all prices in the pharmaceutical industry result from negotiations and are often not transparent to all parties. An invoice price is the amount paid by pharmacies to distributors, and it does not include discounts and rebates separately paid to insurers or PBMs. The net price is the amount that manufacturers actually receive for each prescription after paying rebates to PBMs or insurers. [4] Many insurers contract with PBMs to implement formularies and drugs negotiate contracts for with pharmaceutical manufacturers on their behalf. PBMs also negotiate the price that each plan sponsor (including private insurers, Medicare, and self-insured employers) will pay for each prescription. If PBMs can consolidate negotiating power of many insurance plans, they can get better prices for patients. The financial incentives of PBMs, however, are not always aligned with patients. PBMs often get paid a percentage of the drug price as a rebate and therefore, have an incentive to drive up list prices to get a commensurately larger rebate.

Furthermore, although PBMs often report that they pass 90-100% of rebates that they get from the manufacturers to plan sponsors, [5] in a survey by the Pharmacy Benefit Management Institute, one-quarter of the responding employers reported that they received no portion of the rebates that manufacturers paid to PBMs. [6] Of those that did receive a portion of the rebates, only 40% of employers said they received all (100%) of the rebates negotiated on behalf of their beneficiaries by the PBM. The terms of the contracts between PBMs and employers can vary widely and are a result of complex and confidential negotiations. In fact, many insurers and plan sponsors don't even know the net prices they are paying for a drug|they simply get a check at the end of the year that reflects their total share of any rebates that the PBM negotiated on their behalf. Because of this opague pricing system, plan sponsors can have difficulty knowing if the

prices they pay for drugs are growing as slowly as the IMS-Qunitiles data suggest net prices are.

The ability of a plan sponsor to demand beneficial contract terms (i.e., whether they can get 100% of the rebate passed to them) depends on the plan sponsor's ability to negotiate. If a company can negotiate all of the rebate, they are indifferent to whether the invoice price increases, they only care about net prices. Smaller businesses and plans are less likely than their larger counterparts to be able to demand 100% of the rebates be passed to them, because they have fewer beneficiaries and market power. As a result, higher invoice prices with larger rebates harm smaller businesses and plan sponsors with less market power because they are only able to negotiate a smaller fraction of the rebates and the PBMs can retain the rest.

Furthermore, patients are harmed even more than small business by the growing gap between invoice and net prices. The Quintiles-IMS Health report notes that "[w]hile manufacturer net revenues... have increased only modestly over the past decade, patient exposure to costs has increased dramatically." Patients without insurance usually must pay the entire invoice price (and often an additional mark-up by the retail pharmacy). Because these patients do not have insurance, they are often the most sensitive to pharmaceutical prices and may forgo filling prescriptions due to cost. In fact, a poll from the Kaiser Family Foundation found that nearly 21% of Americans have skipped filling a prescription because of cost. Even patients with insurance are hurt by high invoice prices. When a patient needs a specialty drug or one that is not on a preferred tier in their insurer's formulary, they may be expected to pay a co-insurance that is a percentage of the invoice or list price (e.g. 20% for specialty drugs). [7] The patient often does not see any benefit of the manufacturer rebates in their co-insurance.[8]

In short, the increase in the gap between invoice and net

prices means that patients and businesses without strong negotiating power pay a significantly higher fraction of their drug costs. In addition, middlemen in the pharmaceutical supply chain, such as PBMs, make increasingly higher fractions of drug expenditures at the expense of manufacturers who are doing the drug development.

Single Drugs with High Price Tags Can Distort the Overall Data

In addition, the data in the <u>Quintiles-IMS Health report</u> may not be a complete picture of the pharmaceutical market, as it combines expenditures for both generic and brand drugs. While net per capita spending may be relatively constant, the report notes that per capita spending on biologics and specialty drugs has become an increasing portion of overall drug expenditures and now represents almost 40% of per-capita drug spending. Overall, the cost of most medications is decreasing, but the savings are offset by the cost of a few expensive specialty drugs.

For example, the authors of the <u>report</u> discuss how the release of high-priced cures for Hepatitis C, such as Sovaldi, disproportionately increased drug expenditures in 2014 and 2015, so the slowing of drug prices increases in 2016 may only reflect changes in that market. When Gilead Sciences released Sovaldi, its price tag of \$1,000 per tablet or \$80,000 for a course of treatment sparked public outcry. [9] Within 18 months, however, alternative treatments, including Merck's Zepatier and AbbVie's Viekira, entered the field and the list price of Sovaldi fell by 40-60%. [10] Sovaldi and other Hepatitis C treatments may have had a large impact on drug expenditures for just two years, but cases like Sovaldi breakthrough or curative treatments with high price tags - are likely to become more common. For example, the FDA recently approved Kymriah, a gene therapy for Novartis that can treat or cure children with difficult-to-treat or relapsed B-cell precursor acute lymphoblastic leukemia (ALL), but comes with a list price of \$475,000 for a single treatment. This drug has

the potential to extend life expectancy of these patients by many decades, so a cost-benefit analysis might justify the price. Nonetheless, any healthcare system would have difficulty bearing the costs if similar gene therapies become widely used treatments for all cancers.

Conclusion

Reports of slowed growth in net per capita prescription drug prices in recent years should be cause for optimism. A closer assessment, however, sheds light on troubling undercurrents in the data. Patients are facing higher out-of-pocket costs as invoice prices increase much faster than net prices. In addition, the release of curative treatments for Hepatitis C caused a spike in expenditures in 2014 and 2015, making the increase in 2016 look artificially small. As manufacturers develop and market more of these transformative treatments with commensurately large price tags, the costs to the healthcare system may become unsustainable.

These transformative medications can potentially extend the lives of many patients, and are often the result of decades of research by hundreds of scientists in both academia and industry, supported by hundreds of millions of dollars in funding.[11] We want to encourage the development of life-saving medications by rewarding companies for risking billions of dollars on difficult medical problems, but we also need to ensure that patients have access to the medications they need.[12]

In addition to ensuring competition in the pharmaceutical industry, legislators and policymakers must also address the issue that the current system allows drug companies to set prices as they choose. Our nation must seriously consider value-based reimbursement models that include pharmaceuticals on an equal financial basis as other treatment decisions. [1] Quintiles IMS Report "Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021". Published May 4, 2017. Available at: https://www.iqvia.com/institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2016.

[2] Express Scripts 2016 Drug Trend Report. Available at: http://lab.express-scripts.com/lab/drug-trend-report.

[3] Aitken M, Berndt ER, Cutler D, Kleinrock M, Maini L. "Has The Era Of Slow Growth For Prescription Drug Spending Ended?" *Health Affairs*. 2016;35(9):1595-1603.

[4] For a description of different prices used in the pharmaceutical industry see https://www.uspharmacist.com/article/understanding-drug-pricin g.

[5] Adam J. Fein "Solving the Mystery of Employer-PBM Rebate Pass-Through". Drug Channels Blog. January 14, 2016. Available at:

http://www.drugchannels.net/2016/01/solving-mystery-of-employe
r-pbm-rebate.html.

[6] Pharmacy Benefit Management Institute. 2015-2016 Drug Industry Report. Available for download at: <u>https://www.pbmi.com/ItemDetail?iProductCode=2015-2016_BDR&Cat</u> <u>egory=BDR</u>.

[7] The most common payment benchmark is the Average Wholesale
Price, but can depend on the contract arrangements between a
pharmacy and an insurer or PBM. The price may vary between
pharmacies based on their arrangement with the payer (see more
details at
https://www.kff.org/report-section/paying-for-prescribed-drugs
-in-medicaid-current-policy-and-upcoming-changes-currentreimbursement-policy-8593/view/print/ and
amcp.org/WorkArea/DownloadAsset.aspx?id=20668).

[8] Although the new CMS proposed policy changes for the Medicare program may require Medicare Part D plans to pass the value of manufacturer rebates to plans and beneficiaries. For a discussion of this point, see Adam J. Fein "Will CMS Pop the Gross-to-Net Bubble in Medicare Part D with Point-of-Sale Rebates?" Drug Channels Blog. November 21, 2017. Available at: http://www.drugchannels.net/2017/11/will-cms-pop-gross-to-net-bubble-in.html.

[9] Margot Sanger-Katz. "Why the Price of Sovaldi Is a Shock to the System." *The New York Times*. August. 6, 2014. Available at:

https://www.nytimes.com/2014/08/07/upshot/why-the-price-of-sov aldi-is-a-shock-to-the-system.html?_r=0.

[10] Michael Rosenblatt and Henri Termeer. "Reframing the Conversation on Drug Pricing". *NEJM Catalyst*. November 20, 2017. Available at: https://catalyst.nejm.org/reframing-conversation-drug-pricing/ ?utm_campaign=editorspicks&utm_source=hs_email&utm_medium=email&utm_content=5851456 7&_hsenc=p2ANqtz-IH6DHW1E0x0rZXMmXr2AWylALw0fByl_tUBUpk1FVm6Ba UkUAJraZ_f7czBcYT1DycrM0s-508au0bJ1UrnfaV-FYxV1AXCG24V0ZfPfqXzV9l0U& hsmi=58514567.

[11] Ibid.

[12] See the Source's Drug Money Issue Brief 1 for a detailed description of tactics that brand manufacturers employ to stifle competition. Policy makers should employ many legislative and policy solutions to prevent these anticompetitive behaviors, but this post focuses on costs to patients and where there are no alternatives to expensive medications.