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# ISSUE BRIEF

## Improving Market Efficiencies Will Promote Greater Drug Affordability

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## Findings in Brief

Addressing the high cost of medicines in the U.S. is a top policy priority. One approach hopes to make medicines more affordable by capping prices and increasing the government's control over the health care sector. This approach, implemented in many countries, has never led to a system that simultaneously incents innovation and promotes widespread affordability. Often, it achieves neither.

Achieving both of these goals is difficult because innovation is expensive; but, it is possible. For instance, the U.S. market for chemical based medicines (the medicines that are typically sold over a pharmacy counter) has developed a balanced approach that effectively achieves both goals. Innovation is incented because the current system provides a pre-determined exclusivity period that offers innovative companies an opportunity to recoup their costs of capital. Once this opportunity has been provided, the market is then opened up to competition, which drives down the prices of the once-exclusive medicines and thereby promotes widespread affordability. Evidencing how well the chemical-based segment is working, low-cost generic competitors now represent 90 percent of all prescriptions dispensed. This means that while there has been a tremendous amount of innovation, most patients benefit from affordable prescriptions.

Although the market works well for chemical based medicines, the same is not true for innovative biologic medicines, which are cutting-edge medicines derived from living organisms. Biologic medicines are more complicated to develop, and as a result, are the medicines that have been driving the growth in pharmaceutical expenditures. For example, biologic medicines were responsible for nearly 75 percent of the increase in drug expenditures in 2018 based on IQVIA data.

The costs for many biologic medicines remain higher than necessary because the segment is predominantly comprised of innovative originator biologic medicines, with little competition from biosimilars (lower-cost competitors to expensive originator biologic medicines that serve the same role as generics for the biologics market). Consequently, promoting greater use of biosimilars is a necessary reform to reduce the growth in drug expenditures.<sup>1</sup> Inefficiencies that plague the pharmaceutical supply-chain are a significant barrier preventing wider use of biosimilars.

Other problems with the supply-chain also exist and impose adverse impacts on the market, including the market for chemical-based medicines. For instance, due to the complex supply chain, an opaque pricing environment has developed that imposes excessive costs on patients, even if overall expenditures are growing more reasonably. This perverse outcome is enabled by the growing gap between medicines' invoice prices (the prices that manufacturers announce) and their net prices (the prices paid on behalf of patients).

These price gaps exist because the invoice prices announced by manufacturers are not effective market prices. They are more akin to the opening bids of a complex negotiating process. Pharmacy benefit managers (PBMs), on behalf of insurance companies, will then negotiate large discounts and rebates from these list prices (a rebate model). The actual price paid, or the net price, includes these discounts. The discounts have been growing faster than prices over the past decade, and based on IQVIA data, the gap between the net cost of drugs relative to the invoice cost expanded from 13.1 percent of net invoice costs to 28.2 percent. This expanding gap is consistent with the incentives of PBMs because the compensation of PBMs is based on the size of the negotiated discount.

While this process may sound innocuous, several problems arise. Patient costs are often based on the invoice price, not the net price. Since PBMs earn more when the negotiated discounts are larger, they have an incentive to encourage high increases in list prices that are offset with even higher increases in

discounts – the reason for the growing gap between the net cost of drugs and the invoice cost. As a consequence, the costs for patients using the most expensive medicines are rising at a faster rate than the growth in expenditures. Further, patients without coverage do not benefit from the PBM negotiated discounts and can be exposed to the full invoice costs. Basing compensation on the size of the negotiated discount also creates a systemic incentive to favor more expensive drugs that can enable larger discounts, particularly the originator biologic medicines rather than lower cost biosimilars, unnecessarily increasing overall health care costs.

Recent consolidations between the largest PBMs and major health insurers and/or pharmacies are creating additional uncertainty. These consolidations will only serve the interests of patients if the merger improves the business' ability to serve patients. If the mergers are simply a means to further game the current convoluted market structure, then patients' interests will not be well served by these mergers. Within the current opaque supply chain, it is impossible to know which justification is true. If it is the former, then reforms that eliminate the current market inefficiencies will illustrate that the evolving consolidations are efficient, therefore the new corporate structures will continue. If it is the latter, then the reforms will encourage the recent consolidations to be reversed.

Promoting the dual goals of continued medical innovation and greater affordability (particularly for biologic medicines) requires policy reforms that improve market transparency and incent competition in how medicines are delivered to patients. An effective reform that would achieve these goals is transitioning the market from the current rebate model to a net price model. A net-price model ensures that the manufacturer's prices are effective market prices that convey the value of the medicine. The competitive environment will transform from one where manufacturers compete with one another based on a murky discount structure, to one where manufacturers compete based on a medicine's transparent price and its value.

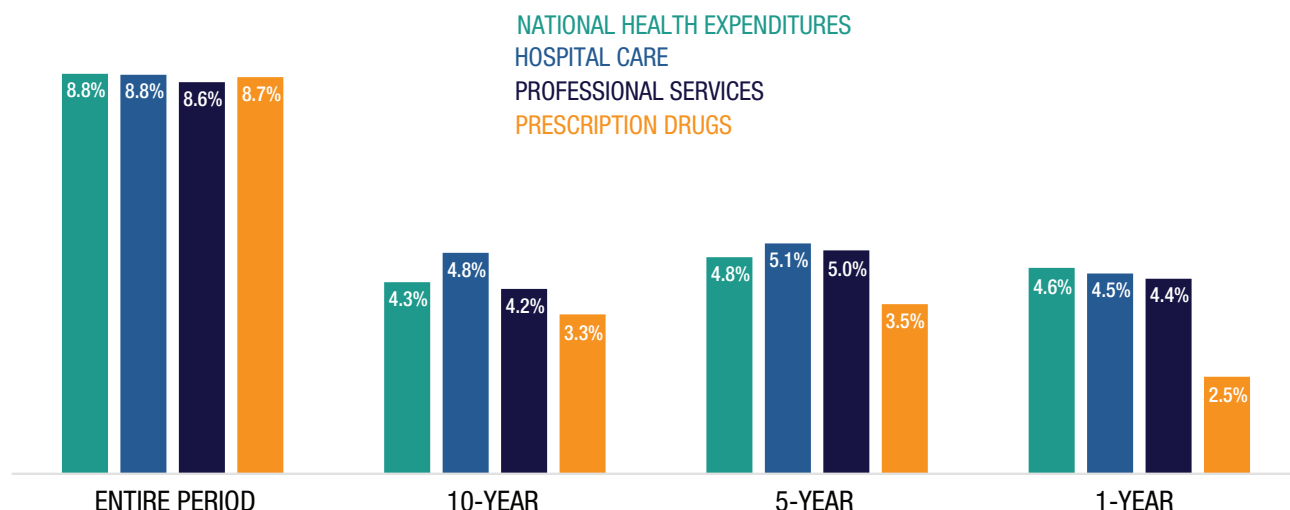
Such a reform directly eliminates the adverse incentives that are currently plaguing the market. As a result, transitioning to a net price model holds the promise of squeezing out the unnecessary costs that have become an excessive burden on the health care system, incenting greater use of biosimilars, and promoting more price competition against originator biologic and patented medicines. Within a more competitive environment, the vertical integration of the PBM industry with payers and pharmacies will either be justified based on its merits, or these mergers will reverse themselves.

Empowering a more competitive environment for pharmaceuticals is an effective policy reform that will meaningfully bend the drug cost curve for patients and payers while still encouraging continued innovation. Consequently, reforms to the supply-chain that promote greater competition should be a top priority.

## Drug Pricing in Context

Before discussing the inefficiencies enabled by the opaque drug supply chain it is important to recognize that medicines are an integral part of the broader health care system. As such, many of the broader problems increasing health care costs also increase the costs of pharmaceuticals. Recognizing this connection is important because fixing the inefficiencies in the pharmaceutical sector will not fully address the health care affordability problem that plagues the U.S. health care system. And, so long as these systemic biases exist, cost pressures on all segments of the U.S. health care system will persist. This connection can be visualized in Figure 1.

**Figure 1. Average Annual Growth Rates in National Health Expenditures and Select Components, 1960 - 2018**



Source: Author calculations based on Centers for Medicare and Medicaid Services data

Figure 1 presents the average annual growth in U.S. health care expenditures between 1960 and 2018. In addition to the total national expenditures, the growth in hospital expenditures, professional services (e.g. physician services), and prescription drugs are also presented. Figure 1 illustrates that over shorter time periods the growth rates of certain health care components varied from the national average. These discrepancies reflect unique, typically short-lived, factors.

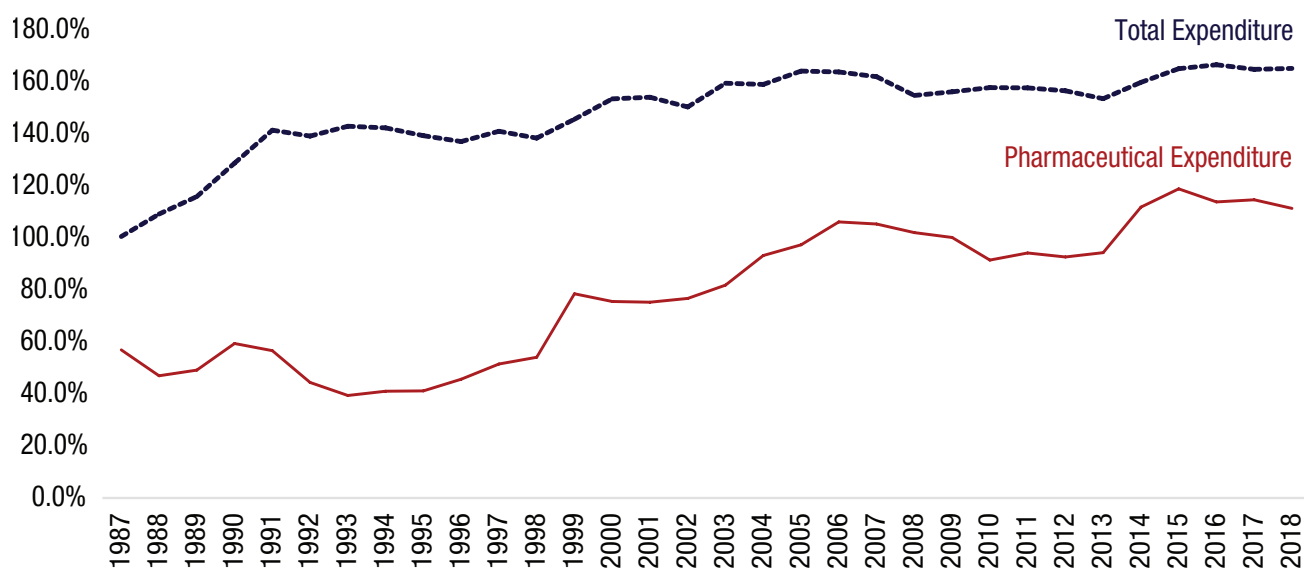
For instance, prices for prescription drugs grew faster than other health care expenditures in 2014 and 2015, which was also a time of increased innovations based on the number of new molecular entities (NMEs) and Biologics License Applications (BLAs) approved by the FDA.<sup>2</sup> But, these trends revert to their long-term averages, and over the past 5-years and the past 10-years the growth in expenditures on drugs has been slower than the other health care expenditures. The 10-year time frame includes “one of the biggest waves of drug patent expirations in history, a phenomenon referred to as the ‘patent cliff.’”<sup>3</sup> In 2018, expenditures on prescription drugs grew 2.5 percent compared to the growth in national health care expenditures (4.6 percent) and hospital care expenditures (4.5 percent).

Despite these short-term trends, the surges and stalls in the growth in pharmaceutical expenditures tend to converge to the long-term growth rate in overall health care expenditures. Since 1960, all of the health care expenditure components examined in Figure 1 grew similarly to overall national expenditures. This outcome makes sense given the interconnection between health care services.

Perspectives on the affordability of pharmaceuticals relative to overall health care can also be gained by comparing U.S. health care expenditures per capita to the average per capita health care expenditures across the Organization for Economic Co-operation and Development (OECD), which is a group of the higher-income market economies. The OECD tracks the per capita expenditures for health care overall (total expenditures), as well as the per capita expenditures on pharmaceuticals (pharmaceutical expenditures). As Figure 2 illustrates, U.S. pharmaceutical expenditures are more affordable relative to other countries compared to total U.S. health care expenditures.



**Figure 2. Per Capita Health Care Expenditures and Per Capita Pharmaceutical Expenditures Percentage Difference Between the U.S. and Average OECD Expenditures 1987 - 2018**



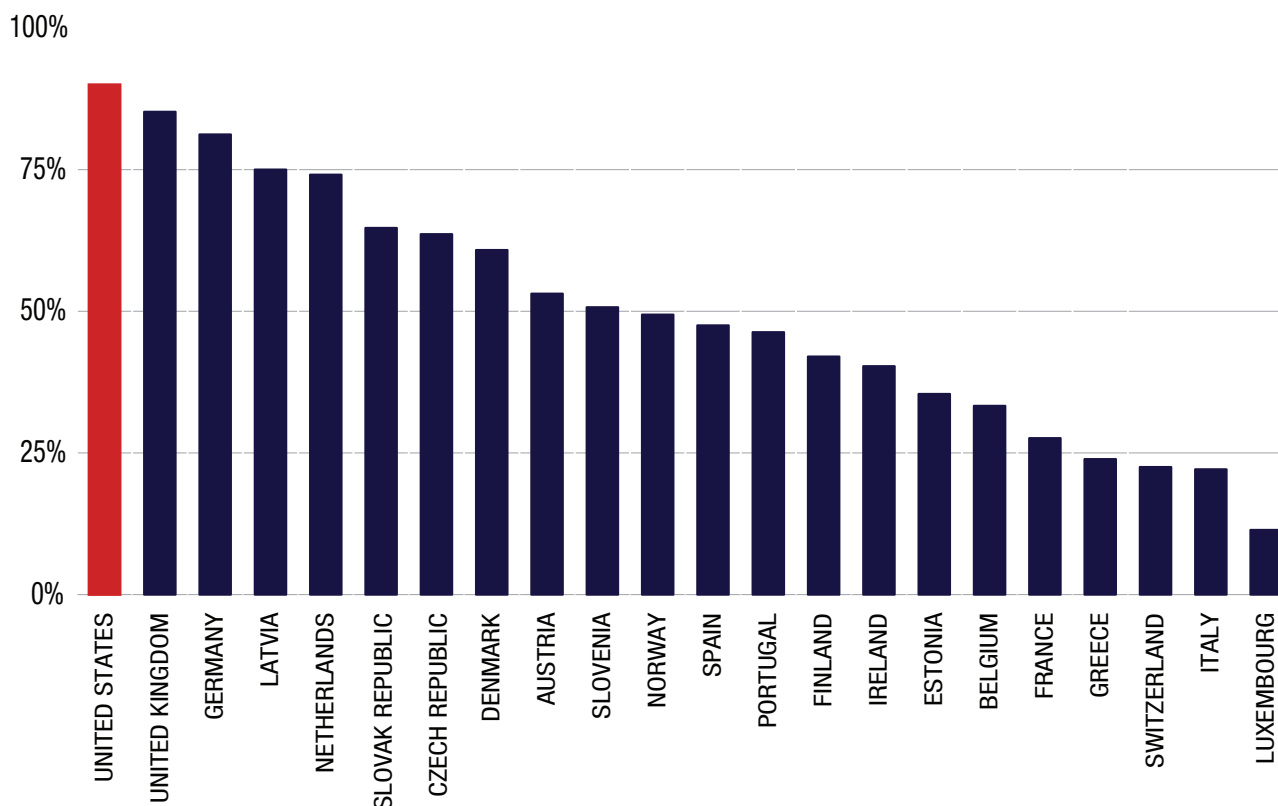
Source: OECD

The red line in Figure 2 presents the percentage difference between pharmaceutical expenditures in the U.S. and the OECD countries. Back in 1987, pharmaceutical expenditures in the U.S. were 56.9 percent higher than the average in the OECD countries. Beginning in 1998 the difference began expanding until as of 2018 U.S. pharmaceutical expenditures were 111.3 percent higher. However, this gap is smaller than the difference between total expenditures in the U.S. relative to the OECD countries. As of 2018, total U.S. expenditures were 165.2 percent higher than the OECD average.

This comparison highlights two important points. First, just like the data presented in Figure 1, Figure 2 confirms that the U.S. has a systemic health care affordability issue that will only be fixed with systemic reforms. Consequently, without addressing the broader problems afflicting the U.S. health care system, efforts to address drug costs are insufficient. Second, relatively speaking, the affordability issue is less for pharmaceuticals than for other aspects of the health care system.

If the affordability issue is less for pharmaceuticals than other aspects of the health care system, then a question naturally arises: what is driving this trend? The answer is the growing market share of lower cost generic medicines. Generic medicines in the U.S. represent 90 percent of all prescriptions by volume, which is the highest generic usage rate among the OECD countries, see Figure 3.

**Figure 3. Generic Market Share by Volume of Prescriptions  
(2016, or latest data available)**



Source: OECD and The Association for Accessible Medicines

Further, 95.3 percent of the generic medicines were filled at \$20 or less, which saves the U.S. health care system \$293 billion annually.<sup>4</sup> Therefore, the exceptionally high-market share of these lower-cost generic medicines are the driving force dampening overall pharmaceutical expenditures. A report by Dobson DaVanzo & Associates (DDA) evaluated the primary drivers of pharmaceutical expenditures using the National Health Expenditure Accounts data since 2009 finding that it is, in fact, the greater use of generic medicines that is generating these systemic savings.

The dominant market share of generics, and the vast majority of these medicines being available at less than \$20 per prescription, illustrates that most U.S. patients have access to affordable medicines. The role generics play in controlling overall drug expenditures demonstrates that market forces are an effective means for the dual goals of promoting pharmaceutical innovation and affordability.

Recognizing the benefits that arise when the systemic incentives support an efficient biopharmaceutical market is important because the biopharmaceutical market is plagued with many problems as well. These problems are either created, or worsened, by the inefficiencies in the current supply chain. For example, due to the opaque and complex supply chain, patients are often spending more on their required co-payments than the actual cost of the drug. According to a 2018 USC Schaeffer Center for Health Policy & Economics report, “in 2013, almost one quarter of filled pharmacy prescriptions (23%) involved a patient



copayment that exceeded the average reimbursement paid by the insurer by more than \$2.00. Among these overpayment claims, the average overpayment is \$7.69. Overpayments are more likely on claims for generic versus brand drugs (28% vs. 6%), but the average size of the overpayment on generic claims is smaller (\$7.32 vs. \$13.46). In 2013, total overpayments amounted to \$135 million in our sample, or \$10.51 per covered life. With over 200 million Americans commercially insured in 2013, these findings suggest the practice of overpayments may account for a non-negligible share of overall drug spending and patient out-of-pocket costs.”<sup>5</sup>

Based on 200 million commercially insured Americans, the USC Schaeffer results imply that in 2013 patients overpaid for their medicines by as much as \$2.1 billion.

There is also the well documented problem of spread pricing. Spread pricing occurs when PBMs reimburse pharmacies at a fraction of what they bill an insurer for the medicine. For instance, a Bloomberg analysis of the spread pricing problem for 90 drugs found that spread pricing “siphoned off \$1.3 billion of the \$4.2 billion Medicaid insurers spent on the drugs in 2017.”<sup>6</sup>

Beyond these problems, the current supply chain is failing to encourage a competitive biologics market, or the innovative medicines that are derived from living organisms. Many of the cutting-edge medical innovations to treat cancer, arthritis, and autoimmune diseases are biologic medicines. These medicines are also driving the growth in drug spending. As the Council of Economic Advisors noted, biologic medicines are “used by only 2 percent of the U.S. population, [but] they have come to comprise between 27 percent and 40 percent of U.S. drug spending (Morton and Boller 2017; Carroll 2013; Purvis and Kuntz 2016).”<sup>7</sup>

IQVIA data confirm that biologics account for a disproportionate share of the growth in expenditures. In 2018, for instance, nearly 75 percent of the increase in total net spending on medicines was due to spending for biologic medicines, see Table 1.<sup>8</sup>

**Table 1. Net U.S. Spending on Medicines, Biologics and Non-biologics, (in billions)**

	2017	2018	CHANGE 2017-18
Non-biologics	\$214.59	\$218.50	\$3.91
Biologics	\$114.60	\$125.50	\$10.90
Net Spending	\$329.19	\$344.00	\$14.81

*Source: Author calculations based on IQVIA data*

Just like generic medicines compete against patented chemical-based medicines driving down their prices, there are competitors known as biosimilars that can compete with the originator biologics and drive down the systemic costs for biologic medicines.<sup>9</sup> It is important to recognize that the process for manufacturing biologic medicines is more complicated and costly compared to chemical-based medicines. Therefore, while substantial price discounts exist, the cost reductions enabled by biosimilars will not be as large as those created by generic medicines relative to patented drugs.

There are many factors biasing the market against biosimilars, but the current supply chain inefficiencies are a significant part of the problem. These inefficiencies discourage the use of biosimilars unnecessarily increasing total expenditures on medicines.

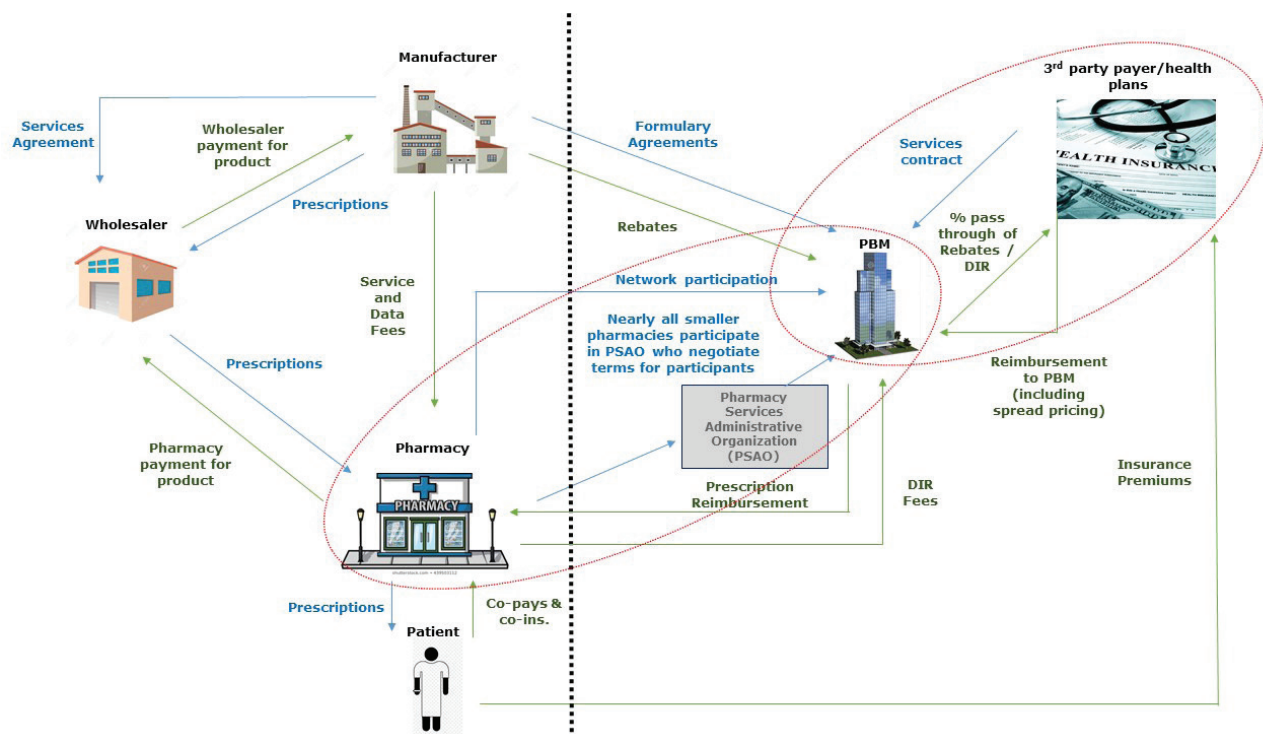
Since the current drug supply chain is creating these types of adverse impacts, it is imperative to understand the current flaws that are driving these outcomes in order to devise remedies that will help reduce the inefficiencies and improve overall drug affordability, particularly for high-cost medicines such as biologics.

## Documenting the Current Complex Supply Chain

Compared to most industries, the pharmaceutical supply chain is excessively complex, as illustrated by Figure 4. Figure 4 is derived from the diagram maintained by *Drug Channels*.<sup>10</sup> The inefficiencies of the pharmaceutical supply chain are exemplified by how difficult it is to follow the flow of payments, prescriptions, and contract agreements.

The supply chains for most industries are summarized by the entities on the left side of the black dotted line in Figure 4. The left side of the figure illustrates that, like most markets, pharmacies (the retailers) receive medicines (the product) from either wholesalers or directly from manufacturers. The pharmacy then sells the medicine to patients. Unlike other markets, the compensation paid directly by the patients, and the payments made by retailers/wholesalers to manufacturers, do not represent the entire financial transaction. Often, these payments are a fraction of the total costs. To understand the entire financial transaction, the right side of Figure 4 has to be incorporated.

**Figure 4. Pharmaceutical Supply Chain**



Source: Derived from the Drug Channels

At the center of the right side of Figure 4 are PBMs or pharmacy benefit managers (PBMs). PBMs' original role was to help create and manage the drug formularies (the list of preferred drugs that determine which medicines patients can use) for insurance companies. By centralizing this function, PBMs' purpose was to reduce the administrative costs for administering and processing a drug benefit program. Leveraging this role, PBMs have expanded their middleman role that, in addition to developing formularies, also includes:

- Negotiating rebates and discounts with manufacturers;
- Determining which pharmacies to include in a drug plan's network;
- Setting the reimbursement rates and fees for network pharmacies; and,
- Operating their proprietary mail order and specialty pharmacies.

Major mergers and acquisitions (M&A) have also taken place in this part of the industry. PBMs are now connected to major pharmacy chains, specialty pharmacies, and health insurers (represented by the red-dotted circles in Figure 4). This M&A activity alters the incentives of the supply chain. For instance, as stand-alone entities, PBMs would have a greater incentive to not pass through all of the discounts and rebates negotiated on behalf of the insurers. When connected to an insurer, this incentive is lessened. The M&A activity also alters the leverage between industry components. To the extent that this changed leverage is used to further exploit the convoluted market structure, the M&A activity could inhibit beneficial reforms.

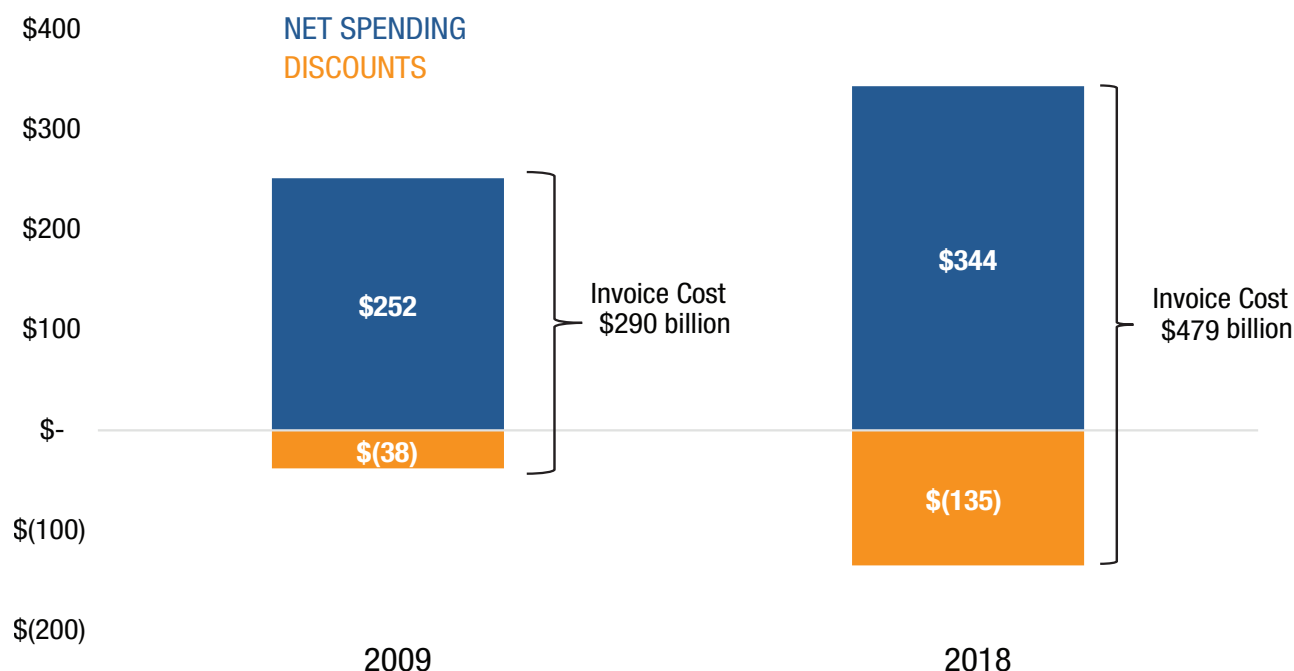
## **Adverse Consequences Created by the Current Supply Chain**

Problems with the current industry supply chain arise because the complicated industry structure creates incompatible incentives that often conflict with the interests of patients. These incompatible incentives arise, in large part, because the pricing structure lacks transparency.

In an efficient market, prices are transparent, which incents suppliers to compete with one another to provide their customers with the price and quality attributes that fulfill consumers' needs. This beneficial market process is missing in the pharmaceutical supply chain. Leveraging their power over the formularies, PBMs negotiate with pharmacies to set their reimbursement rates and fees (often retroactive fees), and negotiate with manufacturers to determine the discounts and rebates off of the list prices. Through these negotiations PBMs are supposed to help control the cost of drugs, but in practice PBMs create a more complicated, less transparent, supply chain that fosters cryptic prices.

While prices for specific drugs are often unclear, there are data that measure the aggregate size of the rebates and discounts. Relative to the total gross expenditures, these rebates and discounts are sizable. According to a Berkeley Research Group (BRG) study, retrospective rebates and discounts accounted for 33 percent of gross expenditures on branded pharmaceuticals, or \$143.7 billion, in 2018, up from 21.9 percent of gross expenditures or \$58.8 billion in 2013.<sup>11</sup> Data from IQVIA confirm the BRG results, see Figure 5.<sup>12</sup> Figure 5 presents the total spending on medicines based on three different measures: the invoice costs, which are the expenditures that would have occurred if not for the total discounts and rebates; the negotiated discounts and rebates; and, the net spending which is the actual spending on medicines that occurred.

**Figure 5. Spending on Medicines: Invoice Costs, Net Spending, and Negotiated Discounts 2009 & 2018**



Source: IQVIA

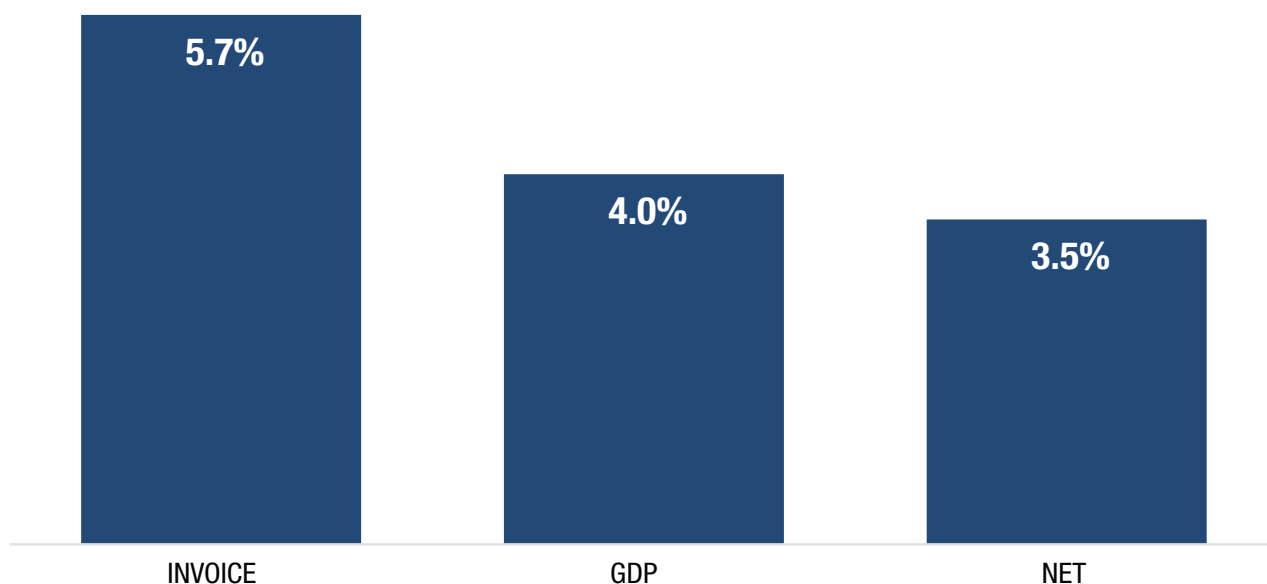
Figure 5 illustrates that over the past decade the size and share of discounts have grown from \$38 billion in 2009 to \$135 billion in 2018. Due to this growth, the spending on medicines based on the invoice costs grew faster (5.7 percent annually, on average) than the actual net spending on medicines (3.5 percent annually, on average). The gap between spending at invoice costs and actual net spending widened from 13.1 percent in 2009 to 28.2 percent in 2018. Supporting the results from the BRG study and IQVIA data, a 2017 report from the USC Schaeffer Center for Health Policy & Economics found that intermediaries receive \$41 for every \$100 spent on prescription drugs.<sup>13</sup>

At first glance, these large discounts appear to support the claims that PBMs are reducing pharmaceutical prices. Looking deeper, these large discounts simply reflect the unwarranted influence PBMs have gained through their control of the drug formularies. Effectively, PBMs have become the medication gatekeepers between doctors and patients. Manufacturers know that without proper formulary placement, patients will not have access to their drugs, and formulary placement depends, primarily, on the size of the discount the PBMs negotiate because PBMs earn more money when they negotiate larger discounts. Consequently, manufacturers are incented to charge high list prices in order to enable large discounts.

On net, these games create a great deal of complexity and confusion. The growth in the spread between invoice costs and net costs also leads to an excessive growth in revenues earned by the supply chain relative to the rest of the industry. The complexity of the supply chain, including the recent industry consolidations discussed in detail below, make it difficult to directly measure these costs. However, the revenue and profit trends of different components of the industry provide evidence that the current structure of the supply chain creates excessive amounts of waste and higher costs.

Starting with the growth in spending, Figure 6 compares the average annual growth in spending on medicines on an invoice and net basis to the average annual growth in the economy, or nominal GDP. Figure 6 illustrates that between 2009 and 2018, the average annual growth in actual spending on medicines (3.5 percent) has been slightly slower than the nominal growth in the economy (4.0 percent). On an invoice basis, the growth on spending on medicines (5.7 percent) has been significantly faster than the growth in the economy. These trends indicate that while the aggregate spending on medicines has been declining relative to the economy, the ability for drug intermediaries to increase their revenues have increased relative to the economy.

**Figure 6. Average Annual Growth Rates in Spending: GDP, Spending on Medicines at Invoice Costs, & Net Spending on Medicines, 2009 - 2018**

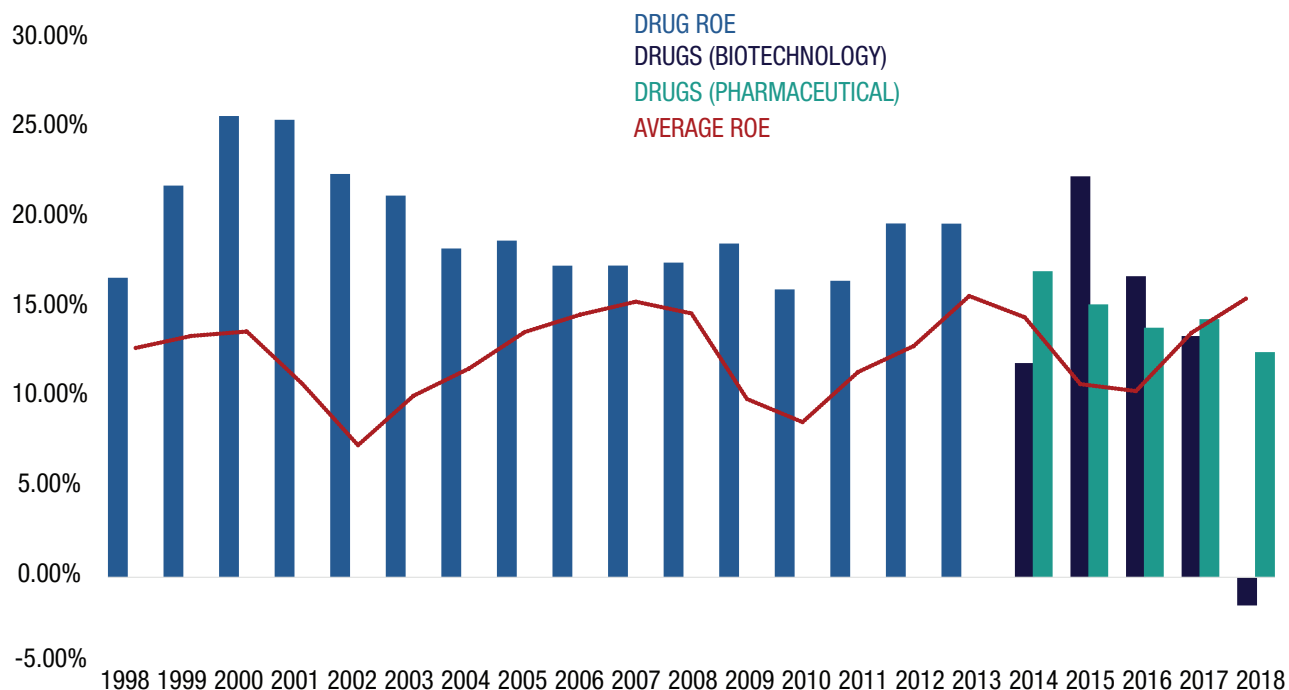


*Source: Author calculations based on data from the BEA and IQVIA*

The change in the profitability of drug manufacturers is consistent with this pattern. Figure 7 presents the return on equity (ROE) for drug manufacturers between 1998 and 2018.<sup>14</sup> Return on equity measures a firm's profitability relative to the amount of equity investors have contributed, a particularly important measure for capital intensive firms.

The black dotted line in Figure 7 tracks the average return on equity for the market overall. While changes in the profitability of the biopharmaceutical industries track market profitability trends, there is also a downward drift in the biopharmaceutical industry's profitability. While the pharmaceutical industry's ROE exceeded the average market ROE in the 1990s and early 2000s, that profitability premium has eroded over time. In 2018, the ROE for both the biotechnology and pharmaceutical industries was less than the average market ROE. It is important to note that this downward drift in the industry's ROE occurred when invoice costs were growing faster than the overall economy.

**Figure 7. Return on Equity: Drug Industry Compared to Market-wide Average  
1998 – 2018**

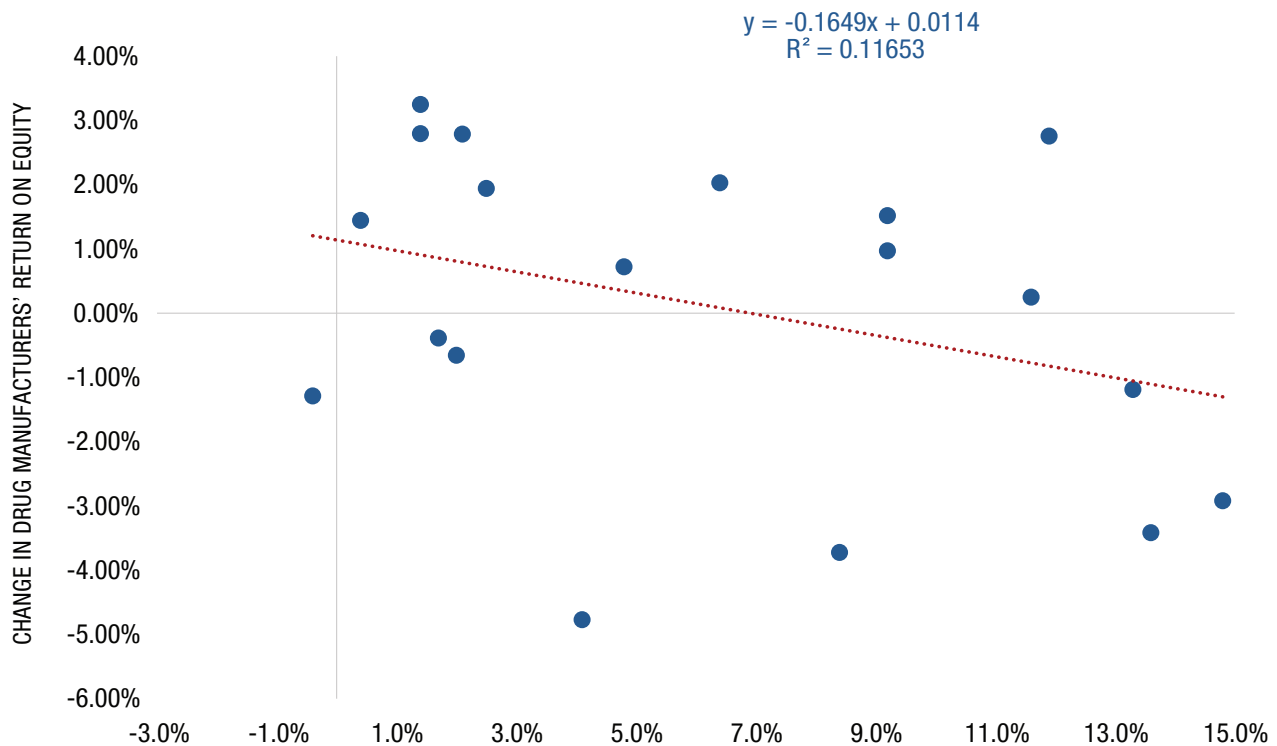


Source: Damodaran Online

Other measures confirm these profitability trends. According to LaMattina (2018), “IRR [Internal Rate of Return] calculates the sales/cash flows resulting from R&D investments, ties R&D and the returns it generates together, and is a more appropriate metric for biopharma productivity. Deloitte reports that the IRR for biopharma R&D has been steadily falling from 10.1% in 2010 to 3.2% in 2017.”<sup>15</sup> Furthering the declining profitability story, the logical positive relationship between rising drug expenditures and rising drug manufacturer profitability has not existed between 2000 and 2018, see Figure 8. Each dot in Figure 8 represents the percentage change in prescription drug expenditures in a year (for example in 2000) as well as the corresponding change in the ROE for the drug industry. Figure 8 illustrates that, if anything, there is a slight negative relationship between rising drug expenditures and changes in industry profitability.



**Figure 8. Change in the Drug Industry's Return on Equity Compared to the Percent Change in Prescription Drug Expenditures, 2000 – 2018**

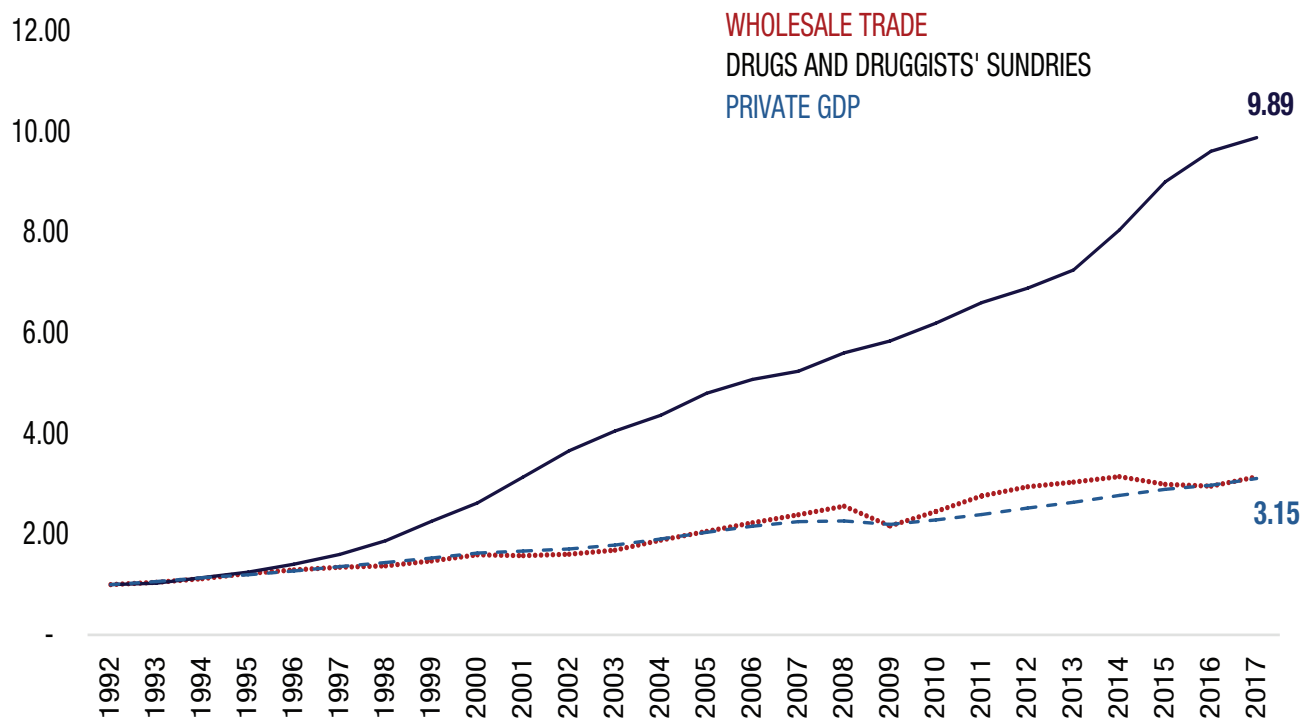


Source: Author calculations based on data from CMS and Damodaran Online

In contrast to the declining profitability numbers for drug manufacturers, the revenue accruing to the drug supply chain is growing faster than the broader economic trends. The rule of thumb in business is to constantly squeeze efficiencies out of the supply chain to ensure the growth in the supply chain remains in balance with overall economic growth. The drug industry has not participated in these trends, as evidenced by Figures 9 and 10. Figure 9 scales the revenue data that the U.S. Census collects in its *Annual Report for Wholesale Trade* to the 1992 industry revenues. Figure 9 presents these data for two categories: for the entire wholesaler industry and for the wholesalers working in the pharmaceutical industry (what the U.S. Census categorizes as “Drugs and Druggists’ Sundries”).<sup>16</sup>

Figure 9 demonstrates that revenues of the wholesale trade in 2017 were around three times the amount of revenues wholesalers earned in 1992, which is around the growth of the private sector economy during this period. In contrast, the revenues for wholesalers in the drug industry are nearly 10 times as high. Consequently, this growth in the size of the supply chain significantly exceeds the revenue growth for the U.S. economy overall, and is at odds with the revenue performance of the broader wholesaler industry.

**Figure 9. Relative Revenue Growth, Wholesale Trade for Drug Industry Compared to Wholesale Trade and Private GDP, 1992 - 2017**

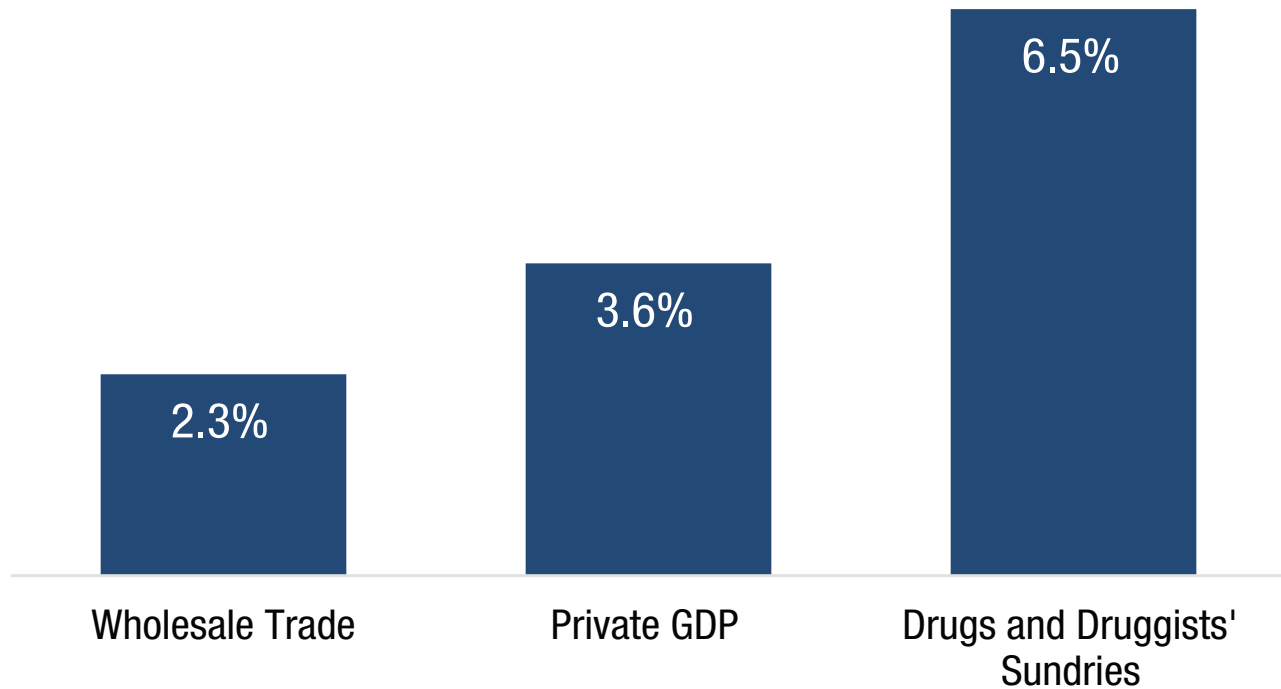


Source: Author calculations based on data from the U.S. Census and BEA

Figure 10 presents the 10-year average annual growth rates for these variables through 2017, which is the latest Census data available. The 10-year average annual growth data confirms that this trend is not simply a historical phenomenon; it continues to persist through the latest data available. In fact, while the average annual growth rate in wholesale trade has fallen below the growth rate for the private economy, the revenues for drug middlemen continue to grow at unjustifiable rates.

**Figure 10. Average Annual Revenue Growth, Wholesale Trade for Drug Industry Compared to Wholesale Trade and Private GDP, 2008 - 2017**

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*Source: Author calculations based on data from the U.S. Census and BEA*

While these data are revenues, not profits, it is important to note that, unlike other parts of the industry, PBMs convert most of their revenues into profits, increasing the overall profitability of these firms. For example, Joyce (2018) argued that:

PBM profit margins are much higher than other players in the supply chain who bear much of the public's anger over rising drug prices. Express Scripts for example, one of the largest PBMs, reported gross profits of \$8.76 billion in 2017. Outside of their mail-order operation, they don't take delivery of the drug. Thus, most of the gross profit converts into EBITDA (earnings before interest, taxes, depreciation and amortization), the standard measure of bottom line profitability. By this metric, Express Scripts and the other major PBMs are living large, both in absolute terms and relative to manufacturers, wholesalers, pharmacies, and insurers.<sup>17</sup>

These data illustrate that something is amiss. A large number of studies that have examined this issue cite the perverse supply chain incentives, particularly with respect to PBMs, as the culprit. In a previous PRI paper, Winegarden (2017), noted that the studies examining the impact from PBMs on the market have generally concluded several adverse impacts from PBMs. Specifically, PBMs:

- Create pricing uncertainty by incentivizing higher list prices for medicines that enable large rebates and discounts (which are particularly valuable for PBMs);

- Cause higher patient co-pays and co-insurance costs than necessary (these costs typically depend on list prices) thanks to the large discrepancy between list prices and transaction prices;
- Push Medicare Part D patients into the coverage gap (donut hole) faster due to the higher list prices;
- Impose large, and often unknown, fees that create substantial revenue uncertainty and volatility, which are particularly problematic for small, long-term care, and specialty pharmacies;
- Increase PBMs' share of the gross expenditures at the expense of pharmacies and manufacturers; and,
- Impose undue influence on the medicines that patients can access through control of the drug formularies.<sup>18</sup>

Further supporting these results, an analysis by Sood et al. (2017) estimated that more than 20 percent of the “spending on prescription drugs goes toward profits of firms in the pharmaceutical distribution system.”<sup>19</sup>

“As evidenced in the excessive growth in the revenues earned by drug intermediaries compared to overall drug expenditures, the large discounts appear to be a mechanism for the supply chain intermediaries to increase their revenues and not a means to lower costs for patients or the broader health care system.

These large profits are enabled, in large part, by the combination of the opaque pricing environment and PBMs' control over the formularies. Unlike a well-functioning market, a portion of these profits come at the expense of other parts of the supply chain, as well as patients. As evidenced in the excessive growth in the revenues earned by drug intermediaries compared to overall drug expenditures, the large discounts appear to be a mechanism for the supply chain intermediaries to increase their revenues and not a means to lower costs for patients or the broader health care system.

As another example, the Council of Economic Advisors (2018) noted that, “the overall [Medicare] Part D benefit structure creates perverse incentives for plan sponsors and pharmacy benefit managers (PBMs) to generate formularies that favor high-price, high-rebate drugs that speeds patients through the early phases of the benefit structure where plans are most liable for costs.”<sup>20</sup> In addition to favoring higher cost medicines, PBMs have also increased drug costs by imposing “murky ‘direct and indirect remuneration’ fees (DIR Fees) charged to providers who dispense

drugs, such as retail and specialty pharmacies and physician-run medical practices that operate retail pharmacies or dispensing facilities (collectively, “Pharmacy Providers”). DIR Fees charged by PBMs to Pharmacy Providers lack any reasonable transparency, threaten the viability of Pharmacy Providers, and, most importantly, increase the cost of drugs to Medicare and beneficiaries.”<sup>21</sup> Expenditures by both patients and Medicare are higher than necessary due to these perverse incentives.

Then there is the problem with the biologics market. As detailed in the “Drug Pricing in Context” section, biologics are driving the increase in drug expenditures. Large potential savings in the biologics market are not being realized, however, because the formularies maintained by PBMs favor the more expensive originator biologics over biosimilars that would be just as effective but cost up to 40 percent less.<sup>22</sup> Recognizing this problem, former FDA Commissioner Scott Gottlieb, M.D. “urged payers to do their part by making biosimilars the default option for newly diagnosed patients.”<sup>23</sup>

Compounding this problem, since most biologic medicines are administered in a clinical setting, they are purchased via a “buy and bill” system. Under this system, the health care provider will buy the medicine and then bill the third-party payer for the costs once the drug has been administered. Typically, the bill is a percentage mark-up of the cost, further increasing the incentive to use the more expensive originator biologic medicine rather than the lower cost biosimilar.

Possibly worsening these problems is the recent industry consolidation that has occurred. Advocates justify the wave of mergers and acquisitions by arguing that integrating PBMs with the operations of an insurer and/or retail pharmacy chain will increase the efficiencies of all of these business lines. Critics argue that the mergers are simply a means to extend PBMs’ market power that has been enabled by the overly complex supply chain. As a result, the critics of the mergers and acquisitions argue that the new combined entities will make it more difficult for pharmacies (particularly small and specialty pharmacies) to compete, further distort the drug price negotiation process, and expose patients to even more cost increases for drugs.

## **Policy Implications – Promote More Competition and Transparency**

Whether the advocates or critics of the industry consolidation are correct matters of course. Given the current industry complexity, there are advantages to the consolidated companies, but whether this industry structure creates efficiencies that patients value is unknown unless reforms improve the competitive landscape. If the consolidated companies can create value to patients in a competitive market, then this would provide unequivocal support to the advocates. If the consolidated firms provided less value to patients in a competitive market, then not only would this provide unequivocal support to the critics, the weaker performance of the consolidated firm would incent these firms to break apart. Either way, promoting a more competitive market would ensure that the industry structure is effectively serving the needs of patients.

The benefits from promoting more price transparency and a more competitive market go further. An overarching theme that connects the trends detailed in the previous three sections is that the complex and ambiguous pharmaceutical supply-chain either creates or worsens the current drug affordability problem. It logically follows that reforms that simplify the current structure, create more competition, and provide more pricing transparency can reduce costs for patients and bend the drug cost curve for the health care system.

Central to this reform is moving to a market that does not rely on the current rebate model. Instead, manufacturers should compete based on the net price (a net price model). Policy reforms that enhance market transparency – such as legislation that would require PBMs to publicly publish the size of their rebates, discounts, and price concessions – could help expedite a transition to a net pricing model for the pharmaceutical industry.

The benefits from a net pricing model is a simpler, more transparent, pharmacy market that eliminates the current systemic disincentives that favor medicines with more expensive list prices but larger rebates. With greater price transparency, patients and doctors will find it easier to recognize the costs of alternative medicines, which creates pressures for PBMs to include the most cost-effective medicines on their formularies. PBMs that exclude lower cost, but just as effective, medicines from the formulary will have to justify these decisions to patients and doctors who would be empowered to hold the PBM (and insurer) accountable for these decisions.

For biologics that are dispensed by pharmacies and administered by patients, a net price model would encourage greater use of lower cost, but just as efficacious, biosimilars rather than the originator biologic medicines. Since biologics are a prime cost driver, removing the systemic bias against biosimilars will meaningfully improve the affordability of drugs. Since most biologics are administered in a clinical setting, to fully reap the benefits from a net pricing model, reforms to the current “buy and bill” system for biologic medicines will be necessary.

Eliminating rebates and requiring price transparency could also fundamentally alter the role of PBMs. Under a net pricing model, the administrative services role of PBMs would be prioritized, and PBMs would be forced to compete with one another to provide the most cost-efficient administrative services to health insurers. Greater competitive pressures will also improve the overall efficiency of PBMs.

“Eliminating rebates and requiring price transparency could also fundamentally alter the role of PBMs.

Increased transparency from a net-price based reimbursement model would also dis-incent other current market inefficiencies. For instance, spread pricing, the practice of charging insurers an amount that is greater than what they reimburse pharmacies, becomes more difficult in a world with transparent prices. To enhance these benefits, the current practice of charging pharmacies hidden (and often retroactive) fees should be prohibited. As with any well-functioning market, all fees should be transparent and known with certainty prior to the transaction.

Finally, a truly competitive market is open to innovations that can fundamentally alter how services are provided. Alternatives could include modifying the manner in which a company works with a PBM, such as the changes made at Caterpillar. Caterpillar created transparency standards for their drug pricing, worked with a PBM that did not engage in spread pricing, and created direct contracts with pharmacies cutting its annual “prescription drug-spend” by tens of millions of dollars.<sup>24</sup> Then there is the Health Transformation Alliance (HTA). The HTA is a group of 50 major corporations, including Caterpillar, that work together to improve the quality of health care for their employees while also lowering the costs. As part of the HTA’s pharmaceutical solutions, the HTA helps employers work with PBMs, increasing transparency and lowering overall drug costs.<sup>25</sup>

Other innovations could completely change the manner in which drugs are purchased. For instance, GoodRx and Blink Health bypass the current intermediaries and negotiate discounts for patients at participating pharmacies. Similarly, Amazon’s purchase of PillPack is an attempt to fundamentally change how people purchase their medicines. Perhaps such services will fail to gain traction, or perhaps they will be successful and meaningfully reduce the current market inefficiencies. Regardless of whether such innovations are successful, competitive markets empower such disruptions in order to maintain the relentless pressure for innovation and improvement.



## Conclusion

Addressing the inefficiencies that plague the pharmaceutical industry is not a panacea that will fix all of the affordability problems that plague the health care system – but it will help. As with most health care expenses, the majority of the excessive drug costs are borne by a small minority of patients. Most prescriptions are generic medicines, which indicates that when most patients are prescribed a medicine, that medicine will cost less than \$20. Recognizing this reality, it is imperative to analyze the efficiency of the drug industry for the most expensive drugs, and identify any inefficiencies that impose unnecessary costs.

This *Issue Brief* reviewed the evidence illustrating that inefficiencies pervade the current drug supply chain that impose large and unnecessary costs on the system. These inefficiencies arise because the current supply chain is overly complex, and prices are not transparent. Consequently, implementing policy reforms that remove these inefficiencies is the most effective way to control pharmaceutical expenditures and still encourage continued medical innovation.

To achieve that goal, an essential reform is to transform the pricing model from the current rebate model toward a net-price model. The current rebate model creates an opaque pricing environment that leads to perverse market incentives. These perverse incentives create anti-competitive practices such as: formularies that favor higher-priced medicines; a payment system that imposes excessive costs on patients and increases the costs for payers including Medicare; the imposition of retroactive fees on pharmacies; and, the practice of charging insurers more than what a PBM paid a pharmacy for the medicine (i.e. spread pricing).

A net price model promotes price transparency, which is sorely lacking. By promoting greater price transparency, a net price model addresses many of the anti-competitive practices and better aligns the incentives of the supply chain with the interests of patients. The result will be medicines that are more affordable for patients today, while still encouraging the innovation necessary to improve patients' welfare tomorrow.

## Endnotes

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