

The prescription drug industry was rocked last month, particularly as it relates to pricing, and it appears this went largely unnoticed.

A wide range of players, from Amazon to Aetna to Express Scripts, announced new business models and acquisitions that are poised to significantly lower drug prices.

Combined with potential FDA action, federal, state, and grassroots-level efforts to increase drug pricing transparency could lower prices for patients. Perhaps, unwittingly, this could even result in a win for President Trump's Drug pricing reform plans.



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IN THIS PAPER, YOU WILL LEARN:

- How current market forces are moving the industry toward price reduction
- The four market forces poised to reveal lower costs for patients
- How emerging business models are reshaping the way the industry will source, price, and deliver prescription drugs



Disruptions and Reductions

On June 28, 2018, Amazon announced its acquisition of PillPack, Inc. for \$1 billion, followed by media commentary from FDA commissioner Scott Gottlieb that "disruptive competition is a good thing." ¹

Even before these announcements, two major planned mergers were moving closer to completion: CVS and Aetna (December 2017) and Cigna and Express Scripts (March 2018). Industry regulations are picking up steam as well with new demands for drug price transparency leading to new legislation, including a proposed amendment to federal bill H.R. 6147 requiring all prescription drug advertising to list drug cost. It is clear that anticipated cost reductions could be driven by pressure generated from the emergence of new business models, industry consolidation, FDA action, and momentum toward drug price transparency (see Figure 2).

While the ground appears to be shifting, it is likely that the impact of these actions will dramatically lower prescription drug costs. As it stands, President Trump's drug pricing reform program seems to be best positioned as the short-term winner. The administration can now point to intensifying market and regulatory activity that is consistent with its formula and likely to lower drug prices and benefit patients.

FOUR MARKET FORCES POISED TO ALTER PRICING

Force 1: New Entrants Bring a New Business Model

Amazon's position to enter the healthcare market is supported by access to a vast amount of resources,

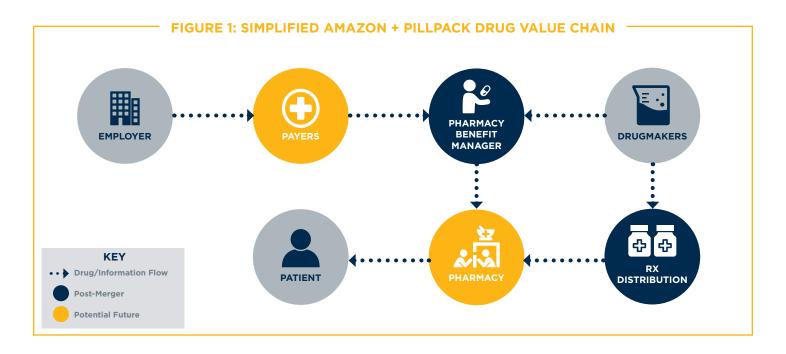


FIGURE 2: FOUR MARKET FORCES DRIVING CHANGE





NEW ENTRANTS: Amazon, Google, and Apple are set to drive the life sciences market to \$1.5 trillion by 2022. In the case of Amazon, it's easy to imagine how its portfolio of joint ventures, acquisitions, and past actions of successfully launching commercial businesses spawned from internal operations; it positioned the company to create a highly efficient pharmacy benefits manager (PBM) with its direct delivery distribution channel. Amazon alone possesses the capabilities needed to replace existing PBMs, distributors, and to some extent, traditional pharmacies. In addition to its potential prowess in the pharmacy space, the joint health initiative with Berkshire Hathaway and JP Morgan also position Amazon to become a provisioner of limited provider services in the future.



VERTICAL CONSOLIDATION: For years, we have seen massive consolidation within each layer in the healthcare value chain, from providers to pharmaceuticals to health plans. What is new, and seems to be accelerating, is the shift to vertical consolidation. Both the CVS acquisition of Aetna and Cigna's acquisition of Express Scripts signal strong moves toward a consolidation of a vertically integrated prescription drug value chain. These acquisitions position both companies to create a highly efficient, proprietary, and payer-centric value chain with deeply integrated partnerships with prescription drug distribution. This model will leverage but eliminate redundancies across drug distribution channels, leading to a more efficient drug supply chain. With these changes, both CVS and Cigna will potentially be able to drive and perhaps force patients into their drug value chain.



FDA ACTION: FDA Commissioner Scott Gottlieb continues to make policies and promote new ideas that are focused on lowering drug prices. In 2017, he laid out an action plan and, as recently as mid-July, has offered new innovative approaches aimed at lowering drug costs.



DRUG PRICE TRANSPARENCY: Lack of drug pricing transparency is widely viewed as contributor to higher prices. Drug value chains have incentives from manufacturers to distribution, PBMs, and payers. These incentives are not transparent, and in many cases, they are not passed on at a lower cost to the patient. Instead, at least part of the incentive is retained as additional profit. Efforts to combat this are emerging at the federal, state, and grassroots levels.



including cash on hand, partnership power from JPMorgan and Berkshire Hathaway, cloud computing, a sophisticated infrastructure, an agile supply chain, and the PillPack acquisition.

This model is characterized by a transformed pharmacy benefit management (PBM) business; a transformed distribution channel that already ships nutritional, OTC and medical supplies and devices; an emerging and highly cost-effective last mile supply chain; and perhaps the ability to ultimately leverage existing brick-and-mortar assets to create new pharmacy operations and clinical services.

A TRANSFORMED PBM BUSINESS

The healthcare joint venture between JPMorgan, Berkshire Hathaway, and Amazon will create an organization like a PBM, but with access to vast amounts of data relating to customer behavior, habits, and disease states. The concept of this business is to create an entity to act as a PBM for their own employee base within the three firms. After building operational capacity and efficiencies, those internal services will be offered to external clients.

This approach is like the cloud business roll-out of Amazon Web Services (AWS). AWS was a highly efficient and radically different business model compared to traditional cloud service providers. As an outsider and new entrant to the technology services arena, Amazon was able to outmaneuver highly reputable, visionary incumbents. Amazon had no clients, no relationships, and no history supporting corporate clients in cloud computing, yet it managed to quickly dominate cloud computing. It accomplished this by combining the successes of its own internal cloud platform with a track record for superior customer—as well as a brand reputation for ease of doing business.

If Amazon, JPMorgan Chase, and Berkshire Hathaway follow the same approach with this new healthcare collaborative, it will not start with a customer base of zero but will begin establishing products and services on a customer base of around 1.2 million collective employees. Once efficiencies are identified and implemented, the collaborative could potentially expand its base into the 5 million sellers on Amazon, and eventually to the 310 million active customers leveraging the Amazon platform alone.

It is conceivable that the collaborative will take aim at rebates, incentives, and modern-day pricing strategies to drive costs down for patients. Through this approach, they could eliminate the current variable-state pricing strategies that are often cited in pharmaceuticals.

One illustrative example:

Pharmacies were paid about \$0.39 per unit of hydroxychloroquine, an immunosuppressive drug, and that amount has decreased steadily since 2015, but PBMs billed Kentucky more than \$2.50 per unit. Additionally, costs for a 6-milligram tablet of paliperidone, a schizophrenia drug, were about \$12 in Ohio; the state was charged more than \$17.50 per unit, as reported by The Columbus Dispatch. The spreads for paliperidone were even larger in Arizona, Indiana, Nevada, and New Hampshire.²

TRANSFORMED DISTRIBUTION SUPPLY CHAIN

The current prescription drug supply chain is inherently inefficient because it is filled out by several "middle men." In simple terms, a drug is moved from the manufacturer to a distribution company, then to a retail pharmacy distribution company, then to a retail store, and finally to the patient's home. This supply chain process tends



to have a high operating cost because of the substantial inventory that each "middle man" holds.

Historically, this model has made sense because of the efficiency gains obtained from shipping bulk product upstream in the supply chain and postponing the smaller packages downstream in the supply chain. However, Amazon has spent a significant amount of time perfecting its supply chain process to serve virtually everyone with overnight service, and now 77.6 million Americans enjoy same-day delivery. As part of the PillPack acquisition, Amazon acquired pharmacy licenses in all 50 states. These pharmacy licenses, in conjunction with Amazon's supply chain, could lead to a highly effective mail-order prescription drug service that eliminates many of the "men in the middle."

ESTABLISHING A PHARMACY STOREFRONT

It is easy to imagine Amazon ultimately moving into pharmacy and clinical services by leveraging its current brick-and-mortar footprint, and perhaps establishing new sites; Amazon has used this strategy before. Once it develops an online business with relative strength and even dominance, it expands to physical sites. In this case, it already has a head start with Whole Foods.

Currently, Whole Foods stores are located in highdensity communities, providing access to a large user base of potential patients. Will Amazon only provide prescription drug services, or will it also provide clinical services at these locations? Overall, this move will require a large amount of capital to implement, but considering the weight of the alliance with JPMorgan and Berkshire Hathaway, capital and infrastructure should be of no concern.

Force 2: The Vertically Integrated Business Model

Legacy healthcare companies have responded to industry disruption by aggressively moving toward vertical consolidation of the drug value chain, and non-providers are even moving into the clinical space. Looking at examples today (CVS/Aetna, Cigna/Express Scripts), it is clear there is an acceleration toward vertical integration. All these moves are intended to drive out operating costs.

In looking solely at the case of CVS, the company is supported by its massive brick-and-mortar pharmacy assets, primary care Minute Clinics, Caremark mail-order services, highly integrated distribution relationships, and now, potentially, Aetna's status as a payer and PBM. The streamlining and rationalization of these businesses will lead to a strong proprietary payer-centric value chain.

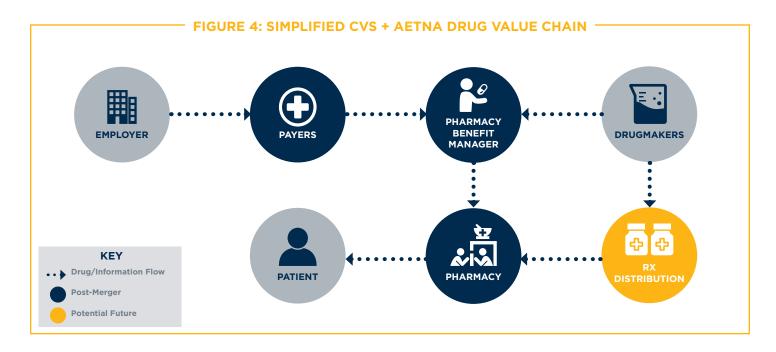
DRIVING PATIENTS TO THEIR CHANNEL

Aetna's coverage of over 37.9 million patients³, combined with around 8,000 CVS locations⁴ and 1,100 Minute Clinics5, is large enough to drive their patients' prescription drug needs through CVS channels. This large patient base and vast infrastructure of low-cost and high-quality services will likely compete with hospitals and other healthcare service companies. All of this means CVS could cut costs while also increasing access to healthcare services by drawing patients to their stores for treatment rather than to emergency rooms.

ALLIANCE-DRIVEN, HIGHLY EFFICIENT SUPPLY CHAIN

Aetna's mail-order delivery services and CVS's pharmacy and Caremark assets position it to create an extremely competitive drug distribution value chain, combined





with deeply integrated alliances and partnerships with drug distributors. CVS Caremark's PBM business, CVS's pharmacy network, and Aetna's health plans all under one roof will provide significant purchasing power over drug manufacturers, which would ultimately lower drug costs within the drug value chain.

INNOVATION AND AGILITY

Combining easier access to low-cost and high-quality services with better patient data from Aetna, this merger should lead to more preventive care for patients and lower healthcare costs within the lifecycle. As this relationship matures over time, CVS will be able to provide new services and offerings throughout its Minute Clinic locations, in turn offering future low-cost options for patients. Lastly, with nearly 7,000 CVS locations without a Minute Clinic presence, a surge of Minute Clinic locations will only provide future savings within the healthcare life cycle.

Force 3: The FDA Takes Action

FDA Commissioner Gottlieb has been passionately looking for ways to reduce prescription drug prices. In 2017, the FDA outlined a number of actions it would take to facilitate price reduction. To date, some of the implemented actions include expedited review of generics, efforts to reengineer the orphan drug process, including expedited applications and new policies to more judiciously grant status, and educating providers on biosimilars in the hope of accelerating acceptance. Although not complete, the FDA has offered to create new guidance on biosimilars that is intended to increase competition by easing the process and potentially creating additional incentives.

In Mid-July, Gottlieb communicated a new idea to reduce drug prices. He offered a potential program to advance access to prescription drugs by creating innovative ways to move them to OTC status. One mechanism for



achieving this is the utilization of technological solutions to move potential low-risk prescription medication to non-prescription status, opening up access and lowering costs for these drug classes.

Force 4: Price Transparency

Price transparency is increasingly becoming a focal point across the healthcare industry, with action now occurring at the federal, state, and grassroot levels.

Just this month, it has been reported that bipartisan support continues to rise for an amendment to H.R. 6147 at the federal level, which requires prescription drug advertisements to be more transparent by communicating costs, illuminating the profits gained in the downstream value chain, and exposing pricing discrepancies across states and health plans. Additionally, there is a growing number of states enacting drug cost transparency laws. Just recently, Maine joined California, Nevada, Oregon, and Vermont in enacting transparency laws.

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If that was not enough, a new firm 46Brooklyn Research has established a drug price database aimed at creating pricing transparency for patients and regulators.

46Brooklyn joins other consumer pricing sites like Lowestmed.com designed to help consumers access lower drug prices. As pricing transparency takes hold, the currently exhibited variance within the drug pricing value chain appears more and more likely to narrow.

Conclusion

Actions to reduce drug pricing are moving fast and are morphing in ways unseen and hard to imagine. Nevertheless, we can likely expect:

- Lower and more uniform prices for prescription and over-the-counter drugs
- The emergence of proprietary value chains where PBMs and payers can nudge or even push patients to purchase drugs
- Consolidation of value chain players into highly efficient, vertically-integrated operations
- New entrants leveraging non-traditional assets and finding new ways to provide services
- Increases in the number over-the-counter drugs, driven by acceptance and acceleration of digital solutions and other innovative approaches
- Additional FDA actions focused on reducing drug prices
- Expansion and acceleration of personalized, highly convenient healthcare services and drugs
- Full transparency and increased uniformity in prescription pricing
- President Trump and the administration claiming success for setting the wheels in motion and perhaps actually reducing drug prices



Finally, incumbents within the current healthcare ecosystem will likely face the "innovators dilemma" where they will have to cannibalize existing profits to create a service that will survive in the future. There are few companies that are able to meet this challenge and come out alive. In the end, new entrants could drive massive change, and ultimately only the incumbents that are able to transform will survive and thrive.

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