Introduction to the Generic Drug Supply Chain and Key Considerations for Policymakers

Key Takeaways

- Generic drugs play an important role in the U.S. health care system, saving payers and patients $253 billion in 2016 and $1.67 trillion over the last 10 years.[1]
- In 2016, 89 percent of all prescriptions dispensed in the U.S. were filled with a generic drug. However, those prescriptions only accounted for 26 percent of total drug costs. Furthermore, generic manufacturers function in a vastly different market from branded companies, where the supply chain captures 64 percent of all revenue on generics, while in the brand market the manufacturers retains 76 percent of revenue.[2]

2016 U.S. PRESCRIPTION REVENUE

- The market dynamics of brand and generic drugs are very different, as the brand industry is generally controlled by one manufacturer with exclusivity, while the generic industry follows a multi-competitor model with drug prices decreasing as more competitors enter the marketplace. As a result, since 2008, generic drug prices have declined by more than 60 percent, while brand drug prices have continued to increase.[3]
- With biosimilars entering the U.S. marketplace and poised to offer additional savings in areas of prescription drug spending that had not been available before, it is more important than ever that a healthy generic drug manufacturing market is cultivated to continue offering savings, assuring supply and broadening access to life-saving medicine for all Americans. Currently, specialty drugs (that is,biologics, complex injectables and complex drugs) make up 42.9 percent of costs although they are used by fewer than 3 percent of patients.[4]
- While the generic drug supply chain and the brand drug supply chain include many of the same stakeholders, there are different financial incentives at play.
- When considering solutions to the rising costs of prescription drugs, it is essential for policymakers to fully understand these differences so that policies can be tailored to the different situations of both the brand and generic markets.

Overview of the Generic Drug Supply Chain

BRAND AND GENERIC DRUGS

When a new drug product is developed and initially marketed, it is protected by a patent, which prevents other companies from marketing a similar product (i.e., based on bioequivalence). These drugs are typically referred to as "branded" or "originator" drugs. Once that protection has expired, other manufacturers may apply to the U.S. Food and Drug Administration (FDA) for approval of their own versions of the drug. "Generic," or multiple-source drugs, are drugs for which the initial patent protection for the active ingredient has expired. Generic companies can also challenge patents ahead of patent expiration to bring more affordable medicines to patients as early as possible. Congress has provided the first company(ies) to challenge such patents with the potential for 180 days of exclusivity to encourage generics to take on the significant risk and expense of such patent challenges.

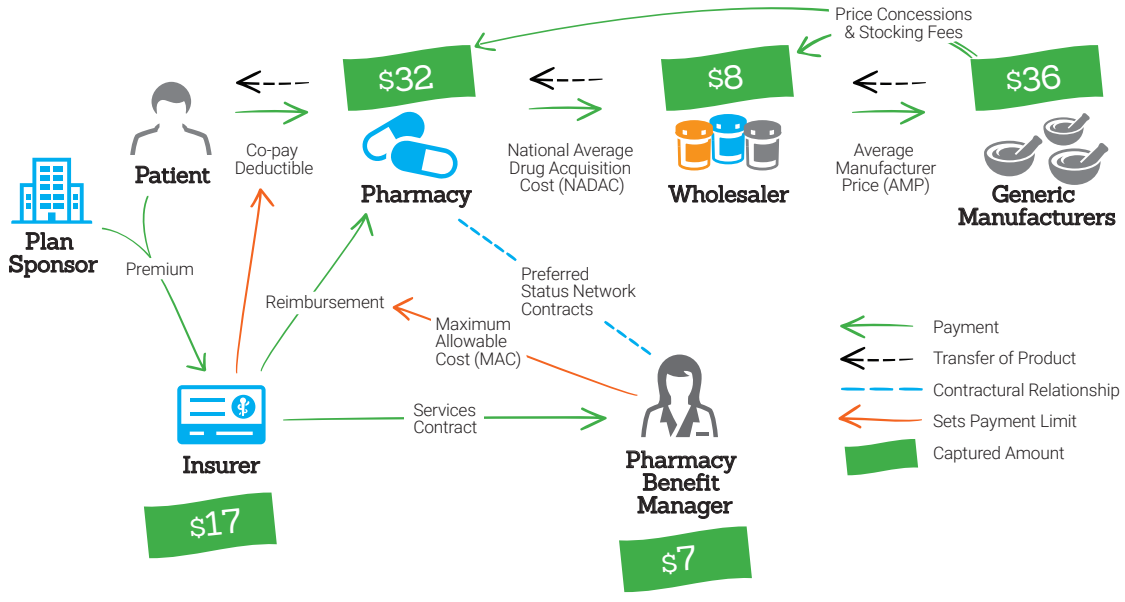
Generic drugs play an integral role in health care. The expiration of patents and the introduction of multiple generic manufacturers competing against each other on price results in significant cost savings for the health care system. Over the last 10 years, generic manufacturers saved the U.S. health care system an estimated $253 billion and $1.67 trillion.[5]

A RECENT INDEPENDENT ANALYSIS RAISES IMPORTANT QUESTIONS ON DIFFERENCES BETWEEN THE BRANDED AND GENERIC SUPPLY CHAINS

While branded and generic drugs take similar paths through the supply chain, there can be different financial incentives facing stakeholders. A recent independent analysis raises several questions about the different market incentives various stakeholders face in the brand and generic markets. Notably, the estimated distribution of money across the stakeholders varies significantly (Figure 1 and 2).[6]

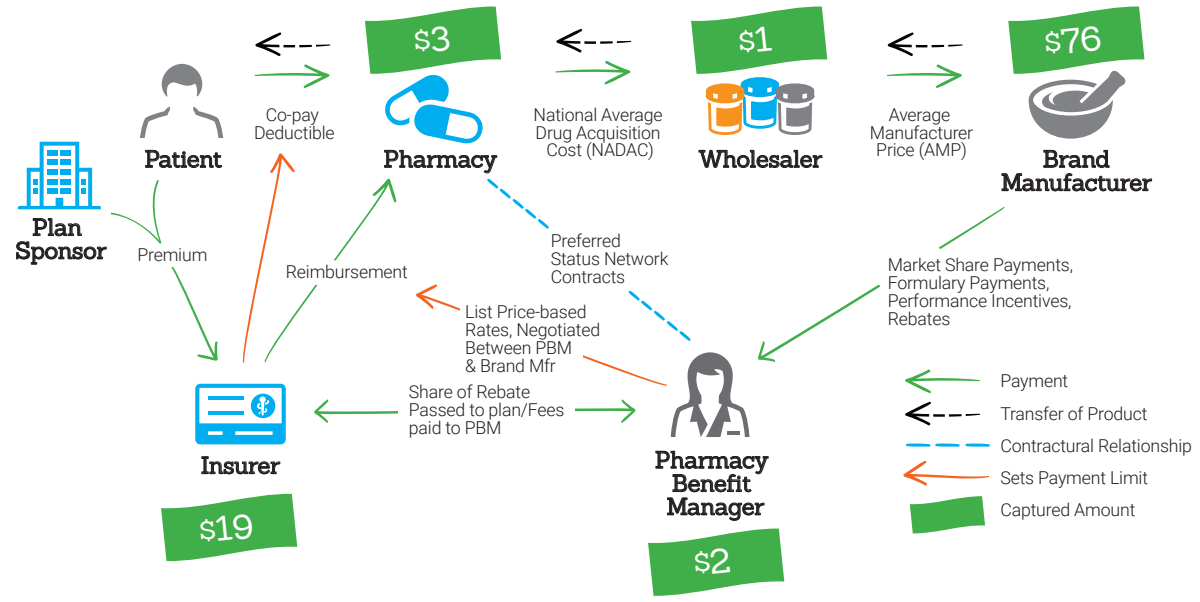
Spread of $100 Across Various Channels in the Generic Drug Supply Chain

Figure 1



Spread of $100 Across Various Channels in the Brand Drug Supply Chain

Figure 2



For example, the manufacturer revenues are responsible for only 36 percent of the final costs for generic products versus greater than 76 percent for the brand products. In the generic market, half the revenue is taken up by production cost, while the majority of the final payer cost for generics is determined by other parties in the supply chain (wholesalers, pharmacies pharmacy benefit managers (PBM), insurers).

There are several reasons for these differences. Branded manufacturers are responsible for bringing new products to market and take on substantial financial risk to do so. Branded manufacturers also operate in a market where there is no direct price competition due to regulatory exclusivities and patent protections. There is little room for wholesalers and pharmacies to capture large margins due to their relative lack of negotiating power. Because pharmacy reimbursement for branded drugs is tied to a reported price for the product, and there is only one product available, price fluctuations do not impact pharmacies in the same way they might in the generic market.

Generic manufacturers take on risk in a different form than the brands, and instead invest heavily to ensure they can demonstrate bioequivalence and incorporate new manufacturing lines. They may also take on significant legal risk by challenging weak brand patents.

However, generic manufacturers are competing against multiple manufacturers of the same product, all of which have been approved by the FDA as bioequivalent. This means that the generic drug market, made up of identical products, experiences competition based solely on cost and ability to supply – giving others in the supply chain, such as pharmacies, wholesalers and group purchasing organizations, greater ability to negotiate competitive acquisition costs and maximize their margins. Due to the large number of generic drugs dispensed – approximately 89 percent of all prescriptions in the U.S. – even a small margin on a drug can result in a large source of revenue due to the volume of product dispensed.

This same dynamic leaves generic manufacturers with relatively little negotiating power. While the number of generic players remains very competitive, the others in the supply chain – wholesalers, pharmacies, group purchasing organizations – continue to consolidate and achieve greater purchasing power with just three of each dominating most of their respective markets. For instance, the purchasing groups that have formed between wholesalers and pharmacies today control about 90 percent of the market share for generic drugs. Because there are multiple manufacturers competing against price, individual manufacturers have little control over the market price at large. This is further complicated by reimbursement for generic products, which is capped and is not directly tied to acquisition cost for individual products.

Manufacturers

Manufacturers are responsible for developing and producing prescription drugs. For branded drugs, manufacturers may be responsible for research and development of new therapies, filing for regulatory approval and marketing approved products. Manufacturers of branded products rely on the revenues generated from the sales of patented drugs to recoup the costs of developing those drugs, and to help fund the development of new drugs. Revenues also finance marketing and promotion costs.

While branded manufacturers must take on substantial financial risk to develop new products, they also have greater control over their price, as they do not have any direct competitors. Generally, branded manufacturers maximize revenue through price rather than volume. For generic drugs, manufacturers are responsible for developing products that meet FDA requirements for approval, as well as producing those products once approved.

Nonetheless, development of a generic drug can be very costly, depending in part on the product, process and dosage form. Generic drugs are required to have the same active ingredient, strength, dosage form and route of administration as the brand name product. Generic drugs must also meet rigorous standards established by the FDA with respect to identity, strength, quality, purity and potency. Finally, generic drugs must have the same quality and performance as brand name drugs. This requires extensive investment in generic drug research and development, manufacturing facilities and equipment, continual maintenance of that equipment and, of course, compliance with quality systems and FDA good manufacturing practice regulations. Moreover, before a generic is launched, brand companies often sue generic companies to try to prevent that launch, causing significant legal fees.

Due to the large number of manufacturers competing against one another on price, prices in the generic drug market can be volatile and are not controlled by a single entity. This volatility in price tends to be downward for the generic industry due to the additional competitors in the market and pricing pressure from others in the supply chain. Pharmacy reimbursement for generic drugs is generally tied to a blended cost of products from all manufacturers, giving pharmacies an incentive to negotiate low acquisition costs from wholesalers and manufacturers.

This difference is highlighted in a report by the University of Southern California's Schaeffer Center for Health Policy and Economics. The center's analysis of the branded and generic supply chains shows that on average a brand manufacturer recoups 76 percent of the prescription drug expenditure on brand drugs, while generic manufacturers capture 36 percent of the expenditure on generic drugs.[7]

Wholesalers

Wholesalers purchase prescription drugs in large quantities from manufacturers. Those drugs are then sold to pharmacies. Wholesalers may also perform other functions for pharmacies, such as logistics and inventory management.[8]

Wholesalers negotiate discounts with manufacturers for the prompt payment of invoices. Wholesalers also generate revenue from sales to pharmacies and fees related to other services provided to customers. Like any other supply chain market, wholesalers can capitalize on price fluctuations – especially those in the generic market.

In contrast to the branded supply chain market, wholesalers capture a larger margin of generic prescription drug expenditures. Wholesalers capture an 8 percent margin, on average, for generic drugs, versus a 1 percent margin on branded drugs.[9]

Pharmacy

Pharmacies are responsible for dispensing prescription drugs to individual patients. Generally, this refers to a retail pharmacy located in the community, but pharmacies can also distribute prescription drugs via the mail, or can serve patients of hospitals, long-term care facilities and community clinics.

Retail pharmacies generate revenue from prescriptions in two ways: any margin between the payment from a patient's health insurance company (or the patient themselves) and the acquisition cost of the drug, and a flat, per-prescription dispensing fee negotiated between a payer and the pharmacy (dispensing fee). Pharmacies can also generate revenue from sales of ancillary goods to patients when they come into the store to pick up their prescriptions.

Pharmacies are typically reimbursed for branded drugs using a listed payment methodology that is tied list to the price of the drug as set by the manufacturer. The primary control on these costs is rebates negotiated by PBMs, rather than any supply chain pressure on sellers. Payers generally reimburse pharmacies for generic drugs using a maximum allowable cost (MAC) methodology. Under this methodology, payers establish a ceiling for reimbursement for each strength and dosage form of a specific active ingredient (for example, 10 mg tablet of atorvastatin). This provides an incentive for pharmacies to acquire generic drugs at a competitive price, but also means that margins on generic products can fluctuate.[10]

Even though reimbursement and acquisition costs for generic drugs can be more volatile than branded drugs, pharmacies realize a much larger portion of the revenue on generic drug expenditures than branded drug expenditures: 32 percent and 3 percent, respectively. They also achieve gross margins of approximately 42 percent and 4 percent on generics and brands, respectively, creating strong incentives for generic dispensing.[11]

Health Plans and Pharmacy Benefit Managers

Health plans are responsible for administering a patient's insurance benefits. In some instances, health plans are financially at risk for health care costs; in other cases, a health plan sponsor (such as an employer) is financially at risk. Health plans determine which items and services are covered, which providers are included in the plan's network and

what the payment rates for each item and service will be. Clinical services, such as disease management and 24-hour nurse lines, are also offered by many plans. Plans also perform administrative tasks, such as claims processing.

PBMs contract with health plans to design and administer a plan's pharmacy benefit. Generally, pharmacy benefits are limited to self-administered prescription drugs (prescription drugs taken by the patient in his or her home), but they can also include physician-administered (prescription drugs administered by a health care professional in an office or clinic setting) in some circumstances. PBMs determine which drugs are covered, and at what cost-sharing level, and also implement utilization management tools (for example, prior authorization, step therapy). PBMs rely on a network of pharmacies, including retail, mail-order and specialty pharmacies, to fill prescriptions for patients. Three of the top six pharmacies are mail-order specialty pharmacies owned by the top three PBMs.[12]

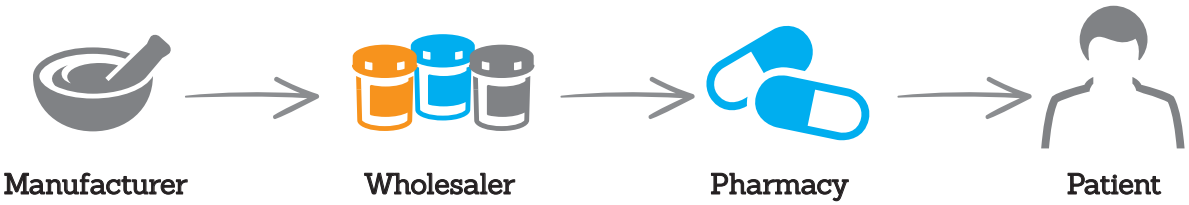
Health plans, or PBMs working on behalf of health plans, typically negotiate rebates with branded manufacturers that are based on utilization. Health plans and PBMs can offer favorable formulary placement (lower cost-sharing relative to other therapeutic equivalents) in exchange for rebates. Manufacturers are willing to offer these rebates in exchange for higher predicted sales to health plan and PBM members.

Due to the unique nature of the generic drug market, it is extremely rare for a generic manufacturer to negotiate rebates with health plans and PBMs. Decisions on which manufacturer to purchase a generic drug from are made at the pharmacy level and do not typically involve a health plan or PBM.[13]

Health plans capture similar shares of revenue from branded prescription drugs and generic prescription drugs: 19 percent and 17 percent, respectively. However, PBMs generate much larger average revenues from generic drugs (7 percent) than from branded drugs (2 percent).[14] The difference is largely created by the different reimbursement methods used in reimbursing brands versus generics. Plans and PBMs largely pass on branded rebates through lower premiums and out-of-pocket costs. At the same time generics are reimbursed based off a MAC list, which sets a ceiling for how much they will reimburse for a generic molecule, allowing them to generally control costs in the generics space and maintain higher margins. These MAC lists, and the methodologies used for maintaining them, are proprietary to the PBMs.

HOW DO PRESCRIPTION DRUG PRODUCTS AND MONEY FLOW THROUGH THE PRESCRIPTION DRUG SUPPLY CHAIN?

Prescription drug products generally flow through the supply chain in the following manner:



However, the flow of spending is a bit more complex.

Health plans and PBMs play an important role in the flow of spending, even though they do not take possession of the prescription drugs themselves. Plans and PBMs are responsible for collecting premium payments from patients and plan sponsors. They are also responsible for paying pharmacies for each prescription dispensed. Depending on their specific plan design, patients typically also owe the pharmacy a co-payment at the time the prescription is filled.[15]

Pharmacies purchase prescription drugs from wholesalers in large quantities at negotiated rates. While pharmacies purchase a supply of prescription drugs from a wholesaler, they are not paid for that product until a prescription is dispensed. Wholesalers purchase products from manufacturers, also at negotiated rates, which could include volume discounts or rebates for prompt payment. They may also provide logistics and inventory management services for their pharmacy customers for an additional fee.[16]

Important Differences Between the Brand-Name Prescription Drug Supply Chain and the Generic Prescription Drug Supply Chain

As mentioned previously, there are several important differences between the brand-name prescription drug supply chain and the generic prescription drug supply chain. These differences can create different financial incentives for stakeholders throughout the supply chain for branded products and generic products.

GENERIC MANUFACTURERS DO NOT NEGOTIATE REBATES WITH PHARMACY BENEFIT MANAGERS AND HEALTH PLANS

One of the most important differences is that generic manufacturers rarely, if ever, negotiate rebates with PBMs and health plans. In the brand drug market, where there is a sole manufacturer, PBMs and health plans will negotiate utilization discounts with manufacturers. Generally, payers will negotiate more favorable coverage (lower cost-sharing, less utilization management) in exchange for larger rebates. These rebates are usually calculated and paid retroactively on past claims.[17]

Because there are multiple manufacturers of a particular drug in the generic market, utilization rebates cannot be negotiated, since the decision of which product to purchase is made by the wholesaler (and ultimately, the pharmacy), not the payer. Therefore, it is difficult, if not impossible, for a health plan or PBM to steer volume toward a particular manufacturer. Generic manufacturers compete against one another to offer the most competitive acquisition cost to wholesalers. Wholesalers are then able to offer that product at a more competitive rate to pharmacies, resulting in a larger volume sold.

PHARMACY REIMBURSEMENT METHODOLOGIES FOR GENERIC DRUGS ARE DIFFERENT THAN FOR BRANDED DRUGS

Another major difference between the branded and generic supply chains is the way that pharmacy reimbursement rates are set by payers. Reimbursement for branded prescription drugs is usually a percentage of a published list price for the drug itself). Because branded drugs are single source, and are only marketed by one manufacturer, the manufacturer can report a price for the product to publicly available pricing compendia.

Each manufacturer of a generic prescription drug sets a unique price for their product (and that price could be further discounted through rebates negotiated with specific wholesalers and pharmacies). Therefore, health plans and PBMs typically establish one single reimbursement rate for a specific dosage and form of a particular drug (for example, 10 mg tablet of atorvastatin) and cap reimbursement at that rate (maximum allowable cost, or MAC). This provides an incentive for pharmacies to purchase the most economically reasonable product, and also puts competitive pressure on wholesalers and manufacturers to sell their product lower than payment rates. Methodologies plans and PBMs use to calculate MAC prices are proprietary, and may be different from plan to plan.[18]

While payment for a branded drug is pegged to the acquisition cost of the drug (and can therefore increase, or decrease, along with price changes from the manufacturer), payment for generic drugs is established using a proprietary formula that could blend acquisition prices among various manufacturers. This dynamic gives branded manufacturers more control over their pricing decisions, while a generic manufacturer competing in a crowded field with multiple other generic manufacturers has less control over their pricing decisions.

Conclusion

It is important that policymakers consider the differences inherent in the branded and generic prescription drug markets when considering public policy changes concerning drug pricing. The differences between the respective markets may require solutions tailored to the specific challenges, rather than a one-size-fits-all solution. In doing so, policymakers should carefully consider how to ensure the sustainability of generic drug markets and a stable supply of lifesaving generic medicines.

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