

What Is Increasing the Cost of Generic Drugs?

(Part I: The Supply Chain)¹

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Compared to spending on doctors and hospitals, prescription drug therapy is a bargain. Generic drugs are especially cheap; accounting for 88 percent of prescriptions filled but only 28 percent of expenditures. Within a year after a brand drug faces competition from generics, the average price falls 80 percent or more.



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Executive Summary

Whereas the average cost of a name-brand prescription was \$268 in 2011, it was only about \$33 for a generic drug.

Intense competition usually holds generic drug prices in check. Oddly, during the past few years, many generic drugs that have been on the market for decades have suddenly become more expensive. The price of more than one-fourth of generic drugs rose 10 percent to 100 percent or more in 2014. In other cases, older generic drugs have become scarce and hard to procure. Some of the reasons for drug price increases fall within the supply chain — the path a drug follows from raw ingredients to the consumer — and are discussed below.

Manufacturers and Market Consolidation. In theory, generic drugs face unlimited competition, since any qualified drug maker can apply to the U.S. Food and Drug Administration (FDA) to produce a generic version of the drug after its patent expires. The reality, however, is often far different. Due to industry consolidation — and an FDA that is slow to approve new entrants into the field — there are many generic drugs for which there are only two or three competing manufacturers.

Informal Collusion and Price-Fixing. When only a handful of producers make a given drug, the opportunities for informal collusion increase. Although it is illegal for competing firms to coordinate pricing, no law is broken when one firm unilaterally raises its price and other firms decide to follow suit.

Drug Wholesalers. The wholesale drug industry has undergone tremendous market consolidation in the past few decades. Today, three large firms control nearly 90 percent of the distribution of wholesale drugs — resulting in less price competition. Drug wholesalers have also been accused of manipulating industry price lists to boost profit margins for themselves and pharmacies.

Pharmacies. Some drugstores also function as small-scale distributors that take advantage of scarcity by diverting drugs in short supply to the wholesale gray market. Pharmacies that would normally buy drugs from wholesalers for resale instead purchase drugs at wholesale with the intention of reselling to hospitals in desperate need of those drugs.

Group Purchasing Organizations (GPOs). Most of the drugs used in hospitals must first pass through a GPO. These firms purchase supplies on

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behalf of numerous hospitals, thereby obtaining lower unit prices on bulk orders. Group purchasers that focus solely on price to the exclusion of having multiple sources of a drug can make the supply chain more fragile. A shortage with associated price spikes can result when a manufacturer loses a bid and exits the market.

Aging Drugs and Niche Therapies. Many of the drugs rising sharply in price are older therapies approved decades ago. Many manufacturers have dropped them either due to low profitability or in favor of newer generics that are in higher demand. In addition, when firms stop production to upgrade equipment, shortages and higher prices often result.

Raw Materials Shortages. Though it is frequently the case that there are multiple manufacturers of a drug, there may be only one or two suppliers of the raw materials used by all producers. Estimates vary, but about 10 percent of drug shortages are thought to be related to raw material shortages.

How Not to Deal with Rising Drug Prices. Today, most health plans include prescription drug benefits. Insurers and employers often hire Pharmacy Benefit Managers (PBMs) to administer drug plans and manage drug costs. PBMs use a variety of techniques to control costs for their clients and plan members. PBMs encourage enrollees to use cost-effective alternatives. They also negotiate with pharmacies and assemble preferred pharmacy networks to manage drug costs and mitigate the problem of rising prices. When price volatility affects local pharmacies, politicians often attempt to insulate drugstores and local constituents from the pain this causes. In the process, state lawmakers often make the situation worse. The following are some harmful regulations that policymakers should avoid.

Banning Efficient Pharmacy Networks. Increasingly, health plans and PBMs reduce premiums by negotiating

and contracting with qualified pharmacies offering competitive prices. Some states have passed *any willing pharmacy* regulations to restrict the right of health plans to contract with exclusive narrow networks.

Restricting Mail-Order Pharmacies. PBMs often use discounts and lower cost-sharing to encourage beneficiaries to use convenient, low-cost mail-order pharmacies. Many state legislatures have tried to ban the use of financial incentives to reward consumers for using low-cost mail-order pharmacies.

Restricting Maximum Allowable Cost (MAC). The wholesale cost of generic drugs can vary tremendously across a year from one manufacturer to the next. So-called MAC price lists are a tool insurance companies use to place an upper limit on plan reimbursements for a given drug. When there is no price limit, pharmacies have little reason to hold costs down since they can pass on the higher cost to drug plan members. More than a dozen states have laws restricting some aspect of MAC lists.

How to Lower America's Drug Bills. Generic drugs are inexpensive when there is competition, but less so when conditions on the supply-side of the generic drug market hamper competition. Market consolidation and long delays at the FDA in processing applications for generic drug manufacturers tend to raise generic drug prices for consumers.

The FDA currently has a backlog of about 4,000 applications. In 2010 the median approval time for new generic drugs was 27 months. The FDA needs to clear the backlog and allow competition to flourish. This, in turn, will alleviate some of the price hikes caused by market consolidation in both drug manufacturing and distribution. Finally, states need to resist pleas from constituents to pass perverse regulations designed to protect local businesses (and pharmacies) at the expense of competition.

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Introduction

Americans consume nearly \$3 trillion of medical care annually, about half of which is spent on physician and hospital care.² Compared to the funds spent on doctors and hospitals, prescription drug therapy is a bargain. Americans spend twice as much for physician care and three times as much on hospital care as they do for drugs. [See Figure I.]

Drugs are also convenient. Most patients prefer medication over surgery to treat significant health problems. Indeed, one of the main reasons many Americans see their doctors is to access prescriptions or to monitor drug therapies. About three-fourths of physician visits result in prescription drug therapy.³

While drugs represent the greatest value in the U.S. health care system, generic drugs are inexpensive compared to alternative forms of care. Generic drugs are often 85 percent to 90 percent less expensive than their name brand counterparts prior to patent expiration. However, many generic drugs have recently increased significantly in price — sometimes for no apparent reason. This report explains the multiple reasons within the generic drug supply chain for the rising costs of generic drugs — and what can be done about it.

Background on Drug Therapies. Drug therapy is the most efficient method to treat most ailments, particularly chronic conditions. Drugs often eliminate, lessen or delay the need for more expensive treatments such as surgery or inpatient care.

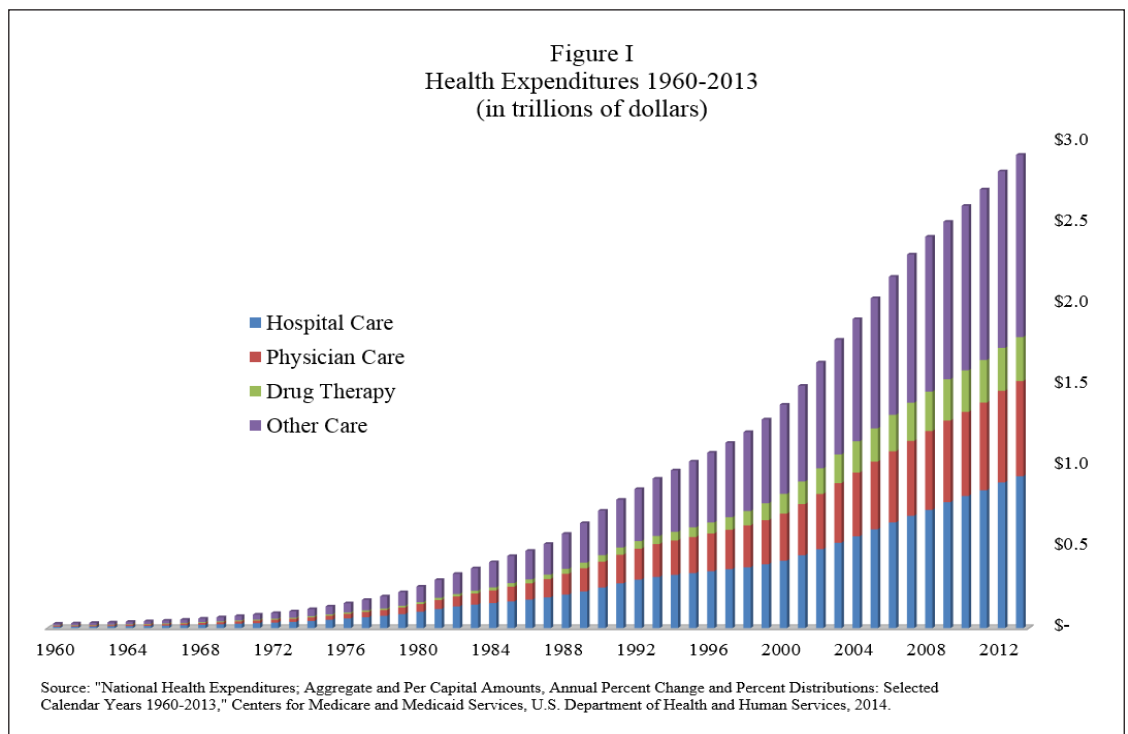
- More than 60 percent of Americans take a prescription drug in any given year, including 90 percent of all seniors.⁴
- An estimated 4.3 billion retail prescriptions were filled in 2014 — about a dozen per person in the United States, on average.⁵

Broader use of prescription drugs for chronic conditions could improve health status and reduce medical costs by avoiding expensive emergency room visits, costly complications and hospitalizations. Spending on prescription drugs has grown tremendously for the past two decades, jumping almost 13 percent in 2014 alone.

- U.S. residents spent about \$329 billion on prescription therapies in 2013, rising to \$374 billion in 2014.⁶
- This is a significant increase from the \$40 billion spent on prescriptions just over two decades ago.⁷

America’s drug bill is expected to continue to rise. Specialty drugs now account for one-third of drug spending, even though they only represent 1 percent of drugs prescribed. Brand drug costs (11 percent of prescriptions) account for 39 percent of drug spending.⁸ Generic drugs account for 88 percent of prescriptions but only 28 percent of drug therapy expenditures. [See Figure II.]

America’s Health Care Bargain: Generic Drugs. Often ignored in discussions of so-called “miracle drugs,” is a type of drug that costs consumers comparatively little and produces benefits far in excess of its cost: generic drugs. Generics include the expensive blockbuster drugs approved years ago that have lost patent protection.

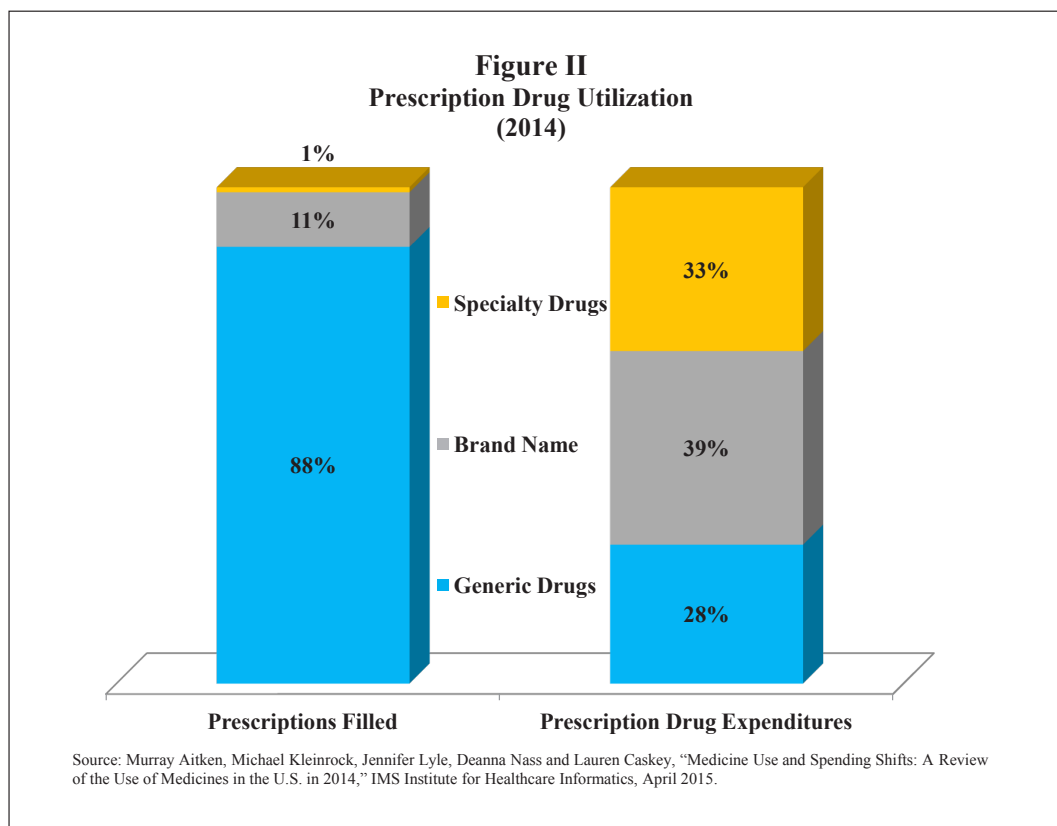


What Is Increasing the Cost of Generic Drugs? (Part I: The Supply Chain)

The Drug Price Competition and Patent Term Restoration Act of 1984 (sometimes referred to as Hatch-Waxman Act) created a pathway for multiple firms to produce generic versions of name brand drugs. When a patent for a branded medication expires, competing firms can submit an abbreviated new drug application to the FDA to produce chemically similar versions. Prior to the Hatch-Waxman, generic drug makers had to perform clinical trials for their generic drugs similar to the innovator drug maker.⁹ Generic drugs are not required to be *identical* to the branded drug they compete with. Rather, they have to be very *similar* in important ways.¹⁰

Recent Generic Drug Prices. Americans spend an estimated \$106 billion annually on generic prescription medications.¹¹ These drugs are generally inexpensive; the average price of a generic drug falls by about 80 percent or more within a year after a name brand drug loses patent protection and faces competition. Compared to branded drugs:¹²

- Though precise estimates are difficult to make, purportedly the average cost of a name-brand prescription was \$268 in 2011.
- By contrast, a generic prescription was much less — only about \$33.
- Whereas the average cost of a branded prescription increased by nearly 18 percent that year, the average cost of a generic prescription fell by 7 percent in 2011.
But that is only part of the story:
- Nearly half of generic drugs declined in price from July 2013 to July 2014, but the remaining half increased in price.
- Some generic drug prices increased dramatically.



- The price of more than one-fourth of generic drugs increased 10 percent to 100 percent or more.¹³ [See Figure III.]
- By comparison, the inflation rate for all other consumer goods rose only about two percent.¹⁴
- Whereas only 3 percent of generic drugs fell in price by 25 percent or more, 18 percent of generic drugs rose in price by 25 percent or more.

In a competitive market with numerous firms competing to sell drugs not protected by patents, prices that rise this quickly should entice other firms to enter the market. Unfortunately, there are numerous reasons why competition is unable to hold prices in check.

Reasons Why Generic Drug Prices Rise: Suppliers

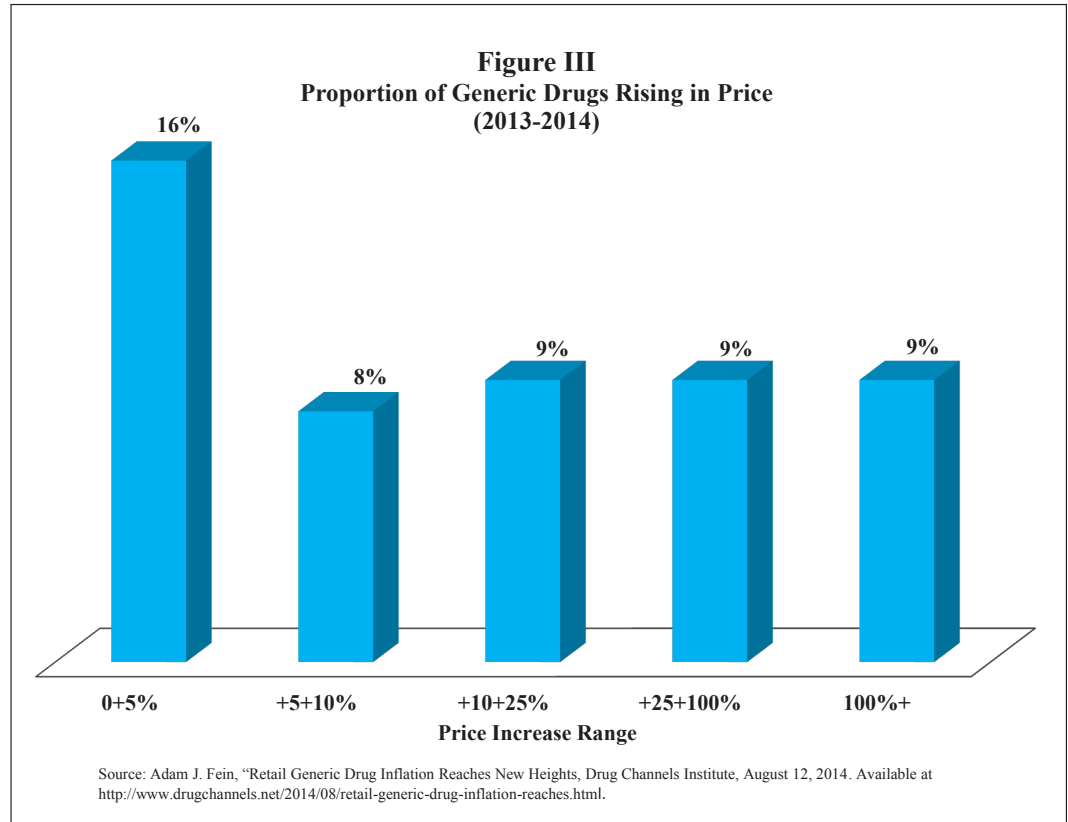
The following are some of the reasons why generic drugs are more costly than they otherwise would be due to conditions before drugs reach the pharmacy shelves.

Generic Drug Manufacturers. The firms that manufacture drugs have a significant — but not absolute — influence over the price.¹⁵ Pharmaceutical

manufacturers are free to establish price levels they believe the market will bear. This is especially true of branded medications protected by patents. There may only be a handful of patented drugs in a given drug class competing for patients. Newer drugs under patent protection often compete with older generic drugs, whose patents have expired. Patented drugs command prices far higher than generics. In theory, generics face unlimited competition since any qualified drug maker can apply to the FDA to produce a generic version when the original drug patent expires. The reality, however, is often far different. Many factors can restrict competition and delay potential competitors from entering the field and producing generic drugs. Drug makers profit when the price of a drug they produce rises. They also gain when competing drugs' prices rise.¹⁶

Market Consolidation and Manufacturers Leaving the Market. A common argument blames market consolidation among generic drug makers for rising drug prices.¹⁷ As firms acquire other firms to achieve economies of scale, the process often leaves only two or three firms making a given drug. With industry consolidation — and an FDA that is slow to approve new entrants into the field — large manufacturers have more market power. With less competition, market consolidation could slowly drive the price of generic drugs higher over time.¹⁸ For instance, research shows the price of a generic drug drops sharply as the number of makers of a given drug rises.¹⁹ [See Figure IV.] It stands to reason that the reverse must also be true; as the number of competitors for a given drug falls, the average price would be expected to rise. However, significant price increases could not be sustained unless new competitors are prevented from easily entering the field. Indeed, that appears to be the case:

- The FDA currently has a backlog of about 4,000



applications to manufacture a generic drug — up about 40 percent from two years earlier.²⁰

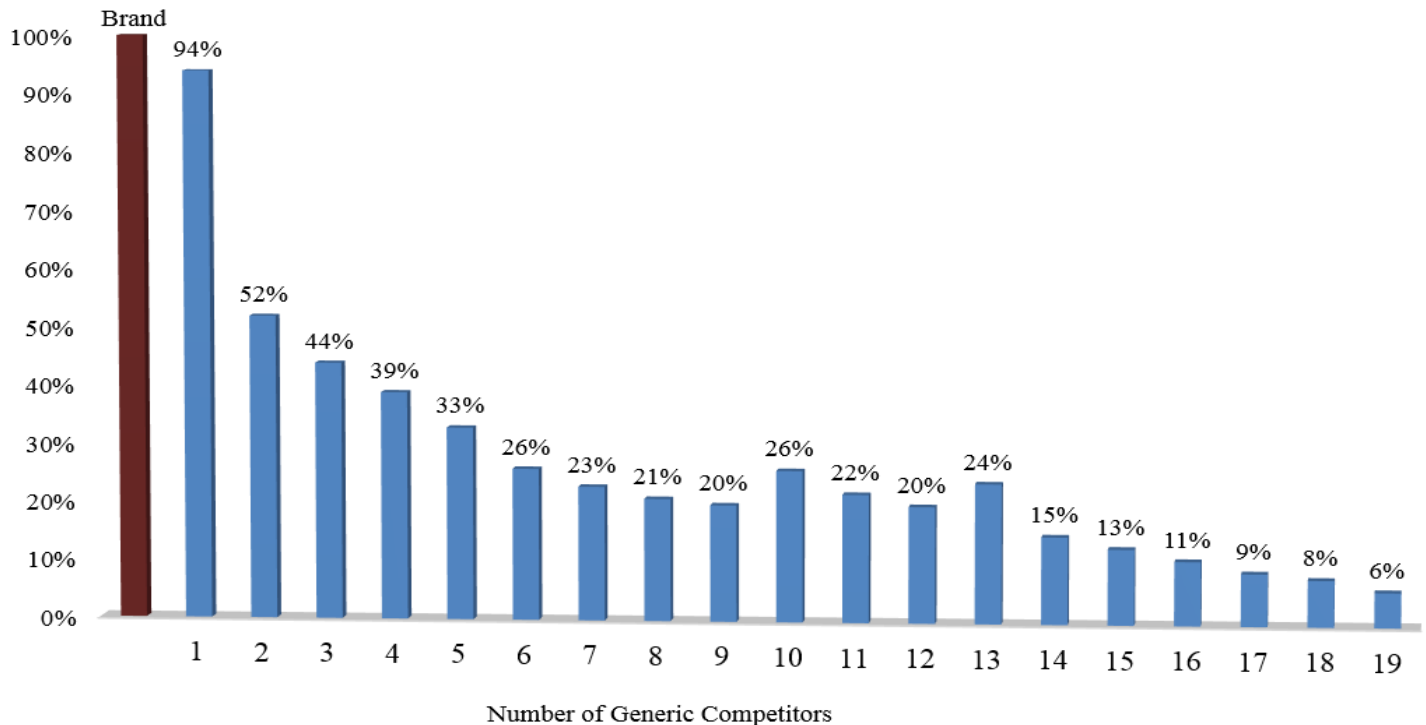
- In 2005, it took the FDA about 16 months to approve a generic drug application.
- In 2010, the median approval time for new generic drugs was more than two years (27 months) including the time lapsed after the FDA requested additional information from the applicant.

In addition, the FDA is also discouraging Indian generic drug makers from entering the market with regulatory hurdles — including banning drugs from the U.S. market made at manufacturing plants owned by Indian drug makers, including Ranbaxy Laboratories Ltd.²¹

Informal Collusion and Price-Fixing. Having only a handful of producers making a given drug increases the opportunities for informal collusion. Collusion and price-fixing are both illegal. For instance, it is illegal for competing firms to form a cartel by agreeing to fix prices at a certain level — and agreeing to never change prices without seeking the approval of the other cartel members. But suppose there are only two or three firms that make a given drug, and one manufacturer

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Figure IV
Generic Drugs Prices as a Percentage of Branded Drug Prices
(by number of competitors)



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005. Cited in Office of the Assistant Secretary for Planning and Evaluation, "Expanding the Use of Generic Drugs," ASPE Issue Brief, Office of Science and Data Policy, U.S. Department of Health and Human Services, December 1, 2010. Available at <http://aspe.hhs.gov/sp/reports/2010/genericdrugs/ib.pdf>.

independently decides to drastically raise its price. No law is broken when the other two firms decide to follow suit — as long as there was no formal agreement or communication to coordinate a uniform increase in price. This may be what happened to Digoxin, an older generic cardiac drug used to treat rapid rhythm disturbances.

Digoxin had been around for many years. Most generic drug makers had stopped producing it, although there was no shortage. By January 2014, only three firms were producing the drug; two of them were small firms. Small firms that derive a significant portion of their income from only a few drugs may view huge price increases as the logical way to boost net income. This is especially true when the firms realize they are in a market with only one or two competitors — who also want to boost profits. Around the beginning of 2014, one of the firms producing Digoxin raised its price and the other two soon followed. By mid-2014, the price of

the drug had doubled from a year earlier, although some patients were faced with prices for the drug that were much higher.²²

Having only two or three manufacturers for a given product not only makes it easier to informally collude, it also makes it easier to illegally collude and fix prices. The federal government is now requiring the makers of Digoxin to provide information regarding any communications that may have occurred with competitors during this period, though the inquiries didn't mention any specific drug products.²³ Employees from two of the companies have already been served with grand jury subpoenas from the Department of Justice (DOJ). Industry insiders suspect the DOJ is preparing for an investigation of price-fixing and other antitrust violations that extends far beyond Digoxin and the two companies.²⁴

Drug Wholesalers. The wholesale drug industry has undergone tremendous market consolidation in the past

few decades. Today, three large firms control nearly 90 percent of the distribution of wholesale drugs.²⁵ This is a huge change from 1975, when there were about 200 wholesalers supplying drugs to chain drugstores and independent pharmacies.²⁶ Market consolidation of this magnitude tends to reduce price competition and make informal collusion among competitors easier to maintain. As a result, pharmacies — especially those that lack significant bargaining power — likely pay higher wholesale prices than would be the case if numerous wholesalers vigorously competed for drugstores’ business.

Having only a handful of large distributors arguably allows distributors to structure the market to their advantage. For instance, only a minority of Americans purchase their drugs directly, whereas drug plans process claims and reimburse pharmacies for the cost of more than two-thirds. The amount a drug plan pays pharmacies for a given drug (and, by extension, what the consumer, insurer or employer ultimately pays) is a function of the drug’s acquisition costs.

Because drug plans cannot monitor every single aspect of drug acquisition, pharmacy benefit managers (PBM) generally base reimbursements on a nationally-recognized standard, such as average wholesale prices (AWP), wholesale acquisition cost (WAC) or a similar measure. Benchmark prices like AWP and WAC are meant to track the average wholesale and average acquisition costs pharmacies across the country pay for their drugs. But these are often not accurate projections of what pharmacies actually pay for their drugs.

Payers complain the precise methodology for calculating AWP has never been defined in statute. Published guides on average wholesale price (and other publications of aggregated cost data) are based on self-reported wholesale price data. It has long been known that published AWP guides are a poor reflection of actual costs pharmacies pay.²⁷ AWP is something of a “list price,” unadjusted for manufacturers’ rebates or bulk purchase discounts. The Office of Inspector General found the average sales price (ASP) is often about half the AWP.²⁸ Indeed, AWP more closely resembles retail prices than wholesale prices.

Drug manufacturers, drug wholesalers and pharmacies all have a vested interest in reporting higher wholesale drugs prices because that pads their profit margins.

Pharmacies stand to benefit because they are reimbursed more than their actual cost. Drug wholesalers benefit from generic drug inflation by shifting price increases onto customers, thereby protecting their own profit margin despite higher costs.²⁹

Consider this: Consumers anticipating the purchase of a car often turn to trusted buyer’s guides that monitor and report average vehicle sales prices, such as the *NADA Blue Book*, *Kelley Blue Book* or *Edmunds.com*. If the average sales prices quoted in buyer’s guides are artificially high, consumers may be lulled into believing the asking prices offered at area car dealers are reasonable — even if the prices are actually higher than is typical. The same can be said of payers reimbursing drugstores based on faulty wholesale price lists.

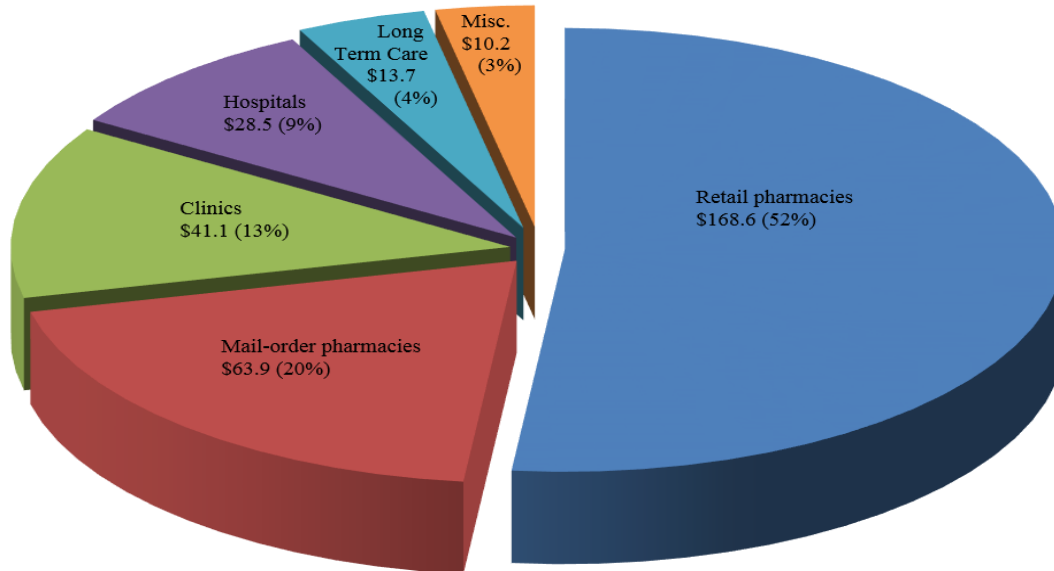
More than a decade ago, McKesson Corporation, a large drug wholesaler, allegedly colluded to fix drug prices with First Data Bank, a publisher of wholesale drug pricing data.³⁰ It is thought the erroneous price data inflated the cost of more than 400 drugs by 20 percent to 25 percent.³¹ McKesson has been sued numerous times over the allegation.³² Largely as a result of scandals and other complaints, many payers have moved away from using AWP as a benchmark for reimbursement. Yet, the potential remains that other standards for reimbursement may also be inaccurate.

Drugs that have risen sharply in price are often those in short supply. Secondary wholesalers — firms that stockpile and resell scarce drugs outside normal distribution channels — also drive up prices, and profit from scarcity when drug prices rise. Though not illegal, these so-called “gray markets” sell drugs without the permission of the manufacturers. In the process, a scarce drug can be relabeled or repacked multiple times, while changing hands four or five times — often under improper storage conditions.³³ Drug stockpiling by secondary wholesalers exacerbates shortages and increases prices unnecessarily.

Pharmacies. Drugstores stand to both benefit and suffer from generic drug inflation. In the short term, profits could be squeezed, but long-term profit margins are likely to rise due to higher prices per script.³⁴ One development that could hurt consumers is consolidation in the drugstore industry. Measured by revenue, the top five drugstore chains control nearly two-thirds of the retail drug market.³⁵

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Figure V
Prescription Drug Spending by Source
(billions of dollars)



Source: Glen T. Schumock et al., "National trends in prescription drug expenditures and projections for 2014," *American Journal of Health-System Pharmacy*, Vol. 71, March 15, 2014, pages e6-e23.

Some pharmacies also function as small drug distributors that do little more than take advantage of scarcity and divert drugs in short supply to the wholesale gray market. When a drug becomes hard to procure due to raw material shortages or manufacturing bottlenecks, some of these small pharmacy distributors buy the drugs with the intention of hoarding them to resell at a substantial profit when the price has increased and the shortage worsened.

Indeed, some of these small pharmacy/distributors are likely created to take advantage of loopholes in state regulatory structures. For example, the so-called "Five Percent Rule" allows pharmacies to wholesale minimal amounts of drugs under various conditions to entities other than patients. Pharmacies sometimes use this loophole to divert scarce drugs to the gray market. It also allows unscrupulous individuals or businesses to avoid registering as drug wholesalers.³⁶ This is not unlike the way ticket scalpers manipulate prices at concerts or sporting events, where the limited supply of tickets exceeds the demand. Pharmacies also attempt to pass on higher drug costs to drug plan members, because individuals with drug benefits pay for only a small portion of their drugs directly. To keep drugs affordable, health plans often employ the services of pharmacy

benefit managers (PBMs), large firms that specialize in designing and managing drug benefits.

Pharmacy Benefit Managers. PBMs use a variety of techniques to control costs for their health plan clients and drug plan members. With multiple clients, large national PBMs can negotiate lower prices from manufacturers, and therefore possess far more bargaining power than individual firms. They also negotiate with pharmacies and build preferred pharmacy networks.

PBMs consult with health plan sponsors to determine which drug therapies to include in their formularies, and to encourage enrollees to use cost-effective alternatives. Within the same therapeutic class, multiple drugs with vastly different costs may be available. This is where generic drugs come in; they are the preferred drug therapy on most formularies. PBMs also check for drug interactions and inappropriate or duplicate prescriptions. Finally, PBMs assemble pharmacy networks, contract with mail-order pharmacies and process payments.

Over the past several years, as the prices of some generic drugs have risen, pharmacy trade associations in many states have petitioned lawmakers to impose additional drug plan regulations. These regulations are designed to make it easier to foist price increases on consumers rather than pharmacies resisting price increases and competing to find lower-priced competing products.

Hospitals. When Americans think of drugs they likely think of neighborhood drugstores but, in fact, hospitals account for 9 percent of national prescription drug expenditures. Drugs used in hospitals are often much different than the pills, capsules and elixirs acquired at

a drug store. Many of the drugs sold in hospitals are not the type patients can self-administer, such as sterile injectable drugs, oncology drugs, anesthesia and so on. Retail pharmacies sell the most drugs, accounting for about half of prescriptions. Drug plan members use mail-order pharmacies for 20 percent of drug purchases. Some patients obtain drugs from clinics (13 percent), while seniors confined to nursing homes may get their drugs from institutional long term-care pharmacies (4 percent). [See Figure V.]

Group Purchasing Organizations. A little-understood stakeholder in the industry that supplies pharmaceutical products to hospitals is the group purchasing organization (GPO). GPOs buy large volumes of medical supplies for distribution to hospitals, including the injectable drugs used in hospital settings.

The concept is rather simple: Allow hospitals to band together and negotiate prices for supplies as a large group rather than as dozens of small buyers. The middleman in this arrangement is the GPO, which negotiates for supplies, often leveraging better prices from a small number of manufacturers in return for sole-source supplier contracts.³⁷ The Government Accountability Office identified the role of group purchasing organizations as a “potential underlying cause” of drug shortages, suggesting GPOs could have an adverse effect on the supply chain of sterile injectable drugs. Group purchasers that focus solely on price to the exclusion of having multiple sources of a drug could — at least in theory — make the supply chain more fragile.³⁸ When one supplier loses a bid for an exclusive contract, it may cease production of a given drug entirely if it has a small market share. The result is that when one supplier shuts down production, there are few others capable of picking up the slack. When there are shortages of generic sterile injectable drugs due to problems at the manufacturer, hospitals are often forced to scramble and pay highly-inflated prices from independent suppliers.

Aging, Second Tier Drugs and Niche Therapies. A common refrain from patients and physicians is that a drug they have used or prescribed for years has suddenly become expensive. A common denominator in the sharply rising price of many drugs is that they are older therapies approved decades ago. [For more details, see Part II of this study (forthcoming).] Many are older classes of drugs that aren’t as widely prescribed.

In many cases, manufacturers have dropped them in order to produce newer generic drugs that are in higher demand. If the consumer is fortunate, the price only doubles. The less fortunate may see prices increase 50-fold. This is what happened with clomipramine, an old tricyclic antidepressant.³⁹

The drugs that have shot up in price include many with a very small market. For example, Albendazole is an antiparasitic medication approved for sale in the United States in 1996, but sold abroad since 1982. Intestinal parasites are not common problem in the United States; thus, the U.S. market for the drug is small. Although the patent expired long ago, no other manufacturer has applied to produce a generic version. A daily dose that would cost about \$1 abroad was nearly \$6 in 2010. By 2013 the price had risen 20-fold.⁴⁰

Raw Materials Shortages. Even if multiple manufacturers produce a certain drug, there may be only one or two suppliers of the necessary raw materials.⁴¹ About 40 percent of finished drugs come from abroad, but about 80 percent of raw pharmaceutical materials are derived from foreign sources.⁴² The quality of pharmaceutical ingredients from foreign sources can vary.⁴³ The raw material supply chain often runs through Asia, where political crises, wars, disease outbreaks or weather can affect production of pharmaceutical ingredients or restrict the trade.⁴⁴

As supply disruptions occur, the domestic price of drugs is affected.⁴⁵ It is estimated that 1-in-10 drug shortages are related to raw material shortages.⁴⁶ One shortage was caused by tainted supplies of raw heparin, the active ingredient in blood thinners. In 2008, heparin sourced from raw materials processed in China were found to be contaminated — probably adulterated intentionally — with a hazardous chemical (over-sulfated chondroitin sulfate) that mimics the properties of heparin just enough to pass tests for purity.⁴⁷ A dozen or more drug makers had bought the tainted supplies, resulting in numerous deaths.⁴⁸ Since the heparin scare the FDA has developed tests for the adulterant.⁴⁹ The FDA has identified and banned the products of about 22 Chinese heparin makers thought to have been involved.⁵⁰ To this day the agency closely monitors Chinese heparin suppliers.⁵¹

Another case of a raw materials shortage reducing supplies and driving prices higher is Tetracycline, a

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broad-spectrum antibiotic whose precursor was first discovered in soil-dwelling bacteria in 1947. Within a few short years, it was synthesized and turned into a common antibiotic still in wide use today.⁵² Over a 12-month period (roughly 2014), its price increased about 67-fold (from just under \$0.04 to \$2.34).⁵³ The reason: The only two manufacturers producing the drug in the United States were both having trouble finding active pharmaceutical ingredients.⁵⁴

Consumers and Payers Lose When Generic Drug Prices Rise

Barriers to any form of competition ultimately cost consumers, employers, insurers, drug plans and taxpayers. If prices for employers, insurers and taxpayers rise, consumers will be forced to pay through lower wages, higher premiums or higher taxes. When generic drug prices spike by a factor of 10 they may come down sooner or later. But pricing volatility not only harms cash-paying customers — others are affected too. At least initially, health plans often bear the cost of price escalation. Although PBMs administer drug benefits for approximately 170 million people, once contracts for coverage are signed, there is often no opportunity to renegotiate until the next contract negotiation period.

When inexpensive drugs become more expensive, it doesn't take long before consumers feel the pinch. Generic drugs that increase sharply in price can be moved from a formulary tier with no cost-sharing to one with significant cost-sharing. Patients taking a drug that becomes scarce and expensive may have to ask their doctor for a different drug that may not work as well or has different side effects. Medicare Part D plans may require higher cost-sharing from seniors. High-deductible health plans may require members to meet hefty deductibles before drug coverage begins. Finally, those who lack drug benefit plans may find drugs that once were cents now cost dollars.

Insurers and Health Plans. Today, most health plans include some level of prescription drug benefits. Consumers enroll in health coverage either through employers or the private market; health plans and insurers provide drug benefits that consumers (and workers) pay for indirectly through higher premiums or lower wages.

When consumers walk into their local drugstore,

drug plans reimburse much of these costs. An estimated 70 percent of Americans belong to a drug plan, and relatively few patients are unable to afford their medications. According to industry data:⁵⁵

- Nearly one-fourth (23 percent) of retail prescriptions are fully covered by insurers and require no copayment by the patient.
- An additional one-third (34 percent) cost the patient \$5 or less.
- And three-fourths (78.6 percent) cost the patient \$10 or less. [See Figure VI.]

The proportion of drug expenses Americans pay out of pocket has fallen sharply during the past 30 years. Patients typically pay only about 17 percent themselves from their own funds for their drugs, on average.⁵⁶ The remainder is reimbursed by a drug plan, insurer or by the government.

For the most part, drugs are very affordable for most American consumers — including seniors with multiple prescriptions. The primary reason drugs are affordable is generic drugs. Nearly nine-in-10 prescription drugs dispensed are generics. But this could all change if low-cost generics become more expensive.

Bad Ideas: How Not to Deal with Rising Drug Prices

With the problem of some generic drugs rising in price unexpectedly, drugstores and chain-store pharmacies are turning to lobbyists in an attempt to insulate their industry from the effects. Although generic drug inflation is a problem that ultimately affects drug purchasers, state lawmakers are pressured by constituents who own and operate small neighborhood pharmacies struggling to compete. The following are some common regulations state lawmakers pass to help local drugstores avoid competition and pass on price hike to customers further down the supply chain.

Banning Efficient Pharmacy Networks.

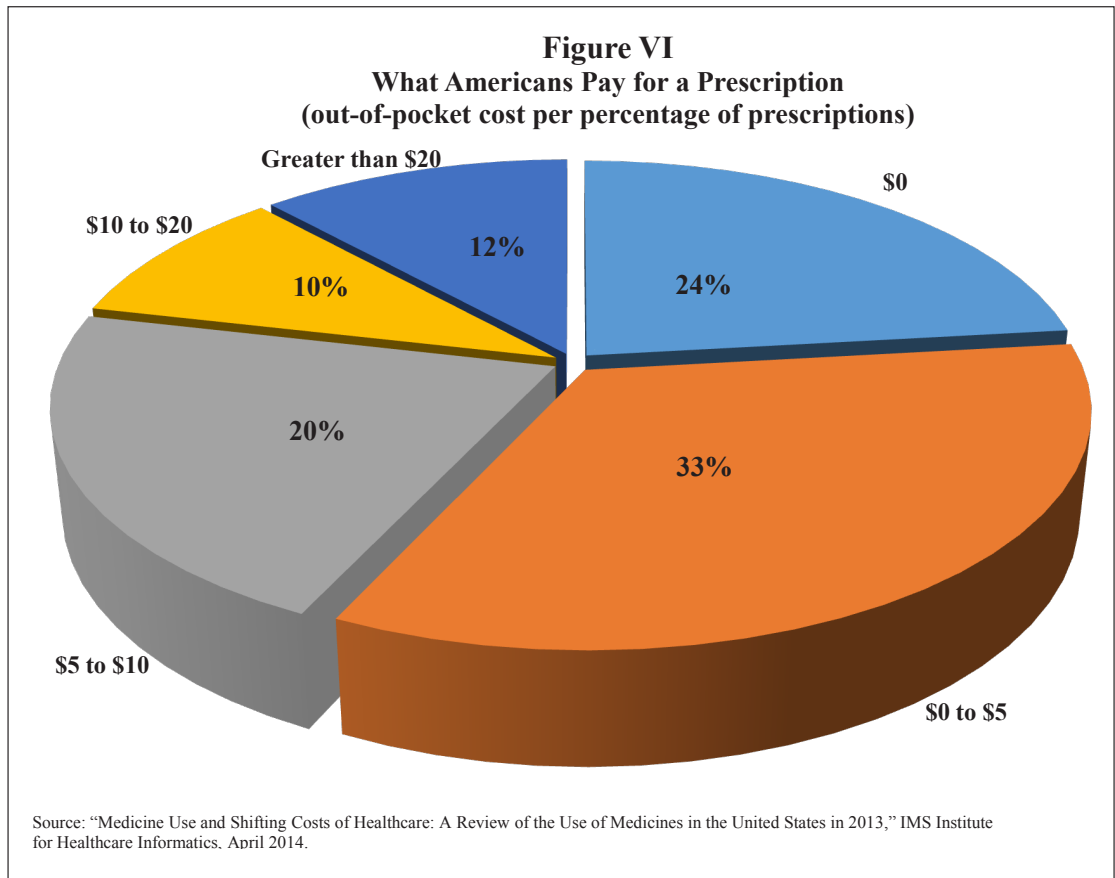
Increasingly, health plans and PBMs have experimented with exclusive or “preferred” pharmacy networks as leverage to negotiate lower drug prices from pharmacies competing to become exclusive network drug providers.⁵⁷ Opponents of this practice argue “open” pharmacy networks offer enrollees more choices and more convenience, and promote competition. However, PBMs counter that the “preferred pharmacies” in

exclusive networks have agreed to deeper discounts in return for the business.⁵⁸

When PBMs create pharmacy networks, they negotiate the lowest possible prices. Negotiated prices are the result of bargaining power — the ability of the drug plan to deny business to a firm if their bid isn't favorable. However, so-called "any-willing-provider" and "retail-choice" laws are designed to reduce pharmacy benefit managers' bargaining power and protect less-efficient pharmacies from competition.⁵⁹ The Federal Trade Commission has argued time and time again — in numerous reports and opinions issued on specific state proposals — that these laws lead to higher drug prices and higher premiums.⁶⁰ In a recent letter to the Centers for Medicare and Medicaid Services, the FTC wrote:⁶¹

"The proposed any willing pharmacy provisions threaten the effectiveness of selective contracting with pharmacies as a tool for lowering costs. Requiring prescription drug plans to contract with any willing pharmacy would reduce the ability of plans to obtain price discounts based on the prospect of increased patient volume and thus impair the ability of prescription drug plans to negotiate the best prices with pharmacies. Evidence suggests that prescription drug prices are likely to rise if Prescription Drug Plans (PDPs) are less able to assemble selective pharmacy networks. The proposed provisions may also hinder the ability of plans to steer beneficiaries to lower-cost, preferred pharmacies and preferred mail order vendors through financial incentives or other terms."

Restricting Mail-Order Pharmacies. Health plans reduce premiums by negotiating and contracting with qualified pharmacies offering competitive prices. Pharmacies and other suppliers excluded from the



network (due to price or quality considerations) lobby sympathetic politicians to force employee health plans, PBMs and insurers to do business with them — boosting costs to consumers. Recent legislative proposals — some that were passed and some that were not — would weaken or prohibit the agreements PBMs negotiate with pharmacy networks.⁶² One way this occurs is through regulations aimed at restricting or prohibiting PBMs from offering drug plan members a financial incentive (a discount) for using a health plan's preferred pharmacy or its mail-order option.

Many states have passed laws designed to benefit local community pharmacies by prohibiting PBMs from rewarding members who use the mail-order option. In 2011, New York State passed Assembly Bill 5502, making it illegal to charge less for mail-order drugs. The law required to reimburse for prescriptions purchased at either local or mail-order pharmacies without consumers incurring additional PBMs cost-sharing or fees.

Restricting Maximum Allowable Cost. More than a dozen states have laws regulating some aspect of maximum allowable cost (MAC) lists. In early March 2015, legislation was introduced in Arkansas (Senate

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Bill 688) that increased the administrative tasks and burdens of drug plans and PBMs when pharmacies serve health plan members.⁶³ The stated reason for the bill was because a few generic drugs were rising in price faster than the MAC list could be updated. Among other things, the new law requires more weekly updates to MAC lists and specifies which drugs could be on MAC lists. It also allows a pharmacy that has contracted with a drug plan to reject prescriptions for unprofitable drugs while filling prescriptions that are profitable, regardless of the contract terms. The proposal went from a senate bill to law in about one month.

At first glance these requirements may not seem problematic, but they could have dire consequences. Pharmacy owners could purposely refuse to fill selected prescriptions. For example, rather than decide to participate or not participate, drugstores could fill customers' prescriptions for some drugs, but purposefully send them away for others — using drug plan members as pawns in a game to force higher reimbursements.

In July 2015, Assembly Bill 627 was passed by the California legislature. The bill requires drug plans to update the MAC list at least one a week. It also regulates the drugs that can be on a MAC list and requires disclosure of how the list is created.⁶⁴ Legislative Document 1150, a regulation debated in Maine, would allow drugs to be on MAC price lists “only if that prescription drug is nationally available and has 3 or more nationally available therapeutically equivalent drug substitutes with a significant cost difference.” That puts the bureaucratic onus of verifying the existence of competitive wholesalers on drug plans rather than expecting drugstores to shop for the most competitive prices. In competitive industries, each purchaser in the supply chain is rewarded for negotiating the best deal possible. This incentive is negated if drugstores can merely pass on higher prices.

The wholesale cost of generic drugs can vary tremendously from one manufacturer to the next. So-called MAC price lists are a tool health plans, drug plans and insurers use to place an upper payment limit on what the plan is willing to reimburse for a given drug. Without a limit, pharmacies would have little reason to hold costs down. If a drug plan was forced to pay whatever cost a drugstore paid for a generic drug, the drugstore would have little reason to look for competitive vendors of generic drugs. In other words, attempts to limit the use of MAC lists inhibits

a tool drug plans used to promote competition among pharmacies. Some state laws attempt to force drug plans to disclose the MAC, and update the list more frequently and sooner. These types of regulations can actually reduce the incentive for drugstores to continually search for the best deals on multisource drugs.⁶⁵ The drug inflation that results is passed on to drug plans, employer plans and ultimately workers and consumers.

More than one-third of states have debated or passed regulations governing MAC pricing in the past several years.⁶⁶ These laws are advanced by pharmacy trade associations to protect the profits of local pharmacies at the expense of employers, insurers, drug plans and consumers.

How to Lower America's Drug Bills. The trade association for generic drug makers sent a letter to the editor the Wall Street Journal *Pharmalot* blog that read, “if Congress wants to explore ways to keep costs down it could increase competition from generics by examining ways to address the growing backlog of generic applications and supporting a biosimilar policy that promotes competition.”⁶⁷ Generic drugs are inexpensive when there is competition, but less so when markets consolidate and the FDA lacks the resources to quickly process competing manufacturers' applications to produce a generic drug.

Conclusion

There are a variety of distinct causes for generic shortages and accompanying price hikes. Some of these are unavoidable as supply chains for raw materials are disrupted by war, famine or natural disasters. Some shortages that cause prices to rise are due to production problems. Some generic drug price spikes are unavoidable as firms update facilities or decide to exit the market.

However, some of the sharp price hikes have little to do with shortages. They are avoidable if the FDA clears the abbreviated drug application backlog and allows competition to flourish. This, in turn, will alleviate some of the price hikes caused by market consolidation in both drug manufacturing and distribution. Finally, states need to resist the call to pass perverse regulations designed to protect local business (and pharmacies) at the expense of competition that benefits consumers, employers, insurers and drug plans.

Notes

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