

Who Is Responsible for Rising Drug Costs?

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by Devon Herrick

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Americans' prescription drug bills are rising. Most drugs are affordable, but prices for a few drugs exceed the average mortgage payment. They can be especially costly when there are only one, two or three patented drugs in a given therapeutic class. Drug makers are free to establish whatever price they believe the market will bear and, depending on the number of competitors, they could have significant pricing power.¹



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The Case of the EpiPen. Consider the recent example of Mylan's EpiPen, which increased about 450 percent in price over a 10-year period. It seems improbable that a 40-year old product would cost more than \$300 apiece.² The EpiPen administers a dose of generic epinephrine worth less than \$1. Though the current EpiPen auto-injector design is under patent protection, generic auto-injectors for diabetics sell for \$30 to \$40 retail. Simple logic suggests an epinephrine auto-injector should cost no more than \$31 to \$41. Yet, EpiPens are only sold in twin-packs at a price of just over \$600 a pair. This kind of pricing power is mostly due to U.S. Food and Drug Administration (FDA) regulations that make it difficult and costly to bring competing products to market. For example, the maker of generic auto-injectors cannot sell syringes preloaded with epinephrine without submitting a new drug application to the FDA and conducting costly clinical trials.

Generic Drugs. Most of the drugs Americans take are generic drugs. Generics are generally inexpensive because they are no longer protected by patents and various manufacturers compete on price. Yet, drugs whose patents have not yet expired can sometimes be very expensive — especially recently approved drugs and biologics derived from living material. Consider:³

- Generic prescriptions account for about 88 percent of prescriptions filled, but only 28 percent of drug spending.
- By contrast, traditional brand drugs constitute 11 percent of drug scripts and 39 percent of drug expenditures.
- The remaining 1 percent of prescriptions are for specialty drugs and account for more than one-third of drug spending.

Thus, nearly three-fourths of all drug spending is on a mere 12 percent of the drugs Americans take.

Some patients face higher drug bills because of rising health insurance deductibles. Higher deductibles make it more difficult for drug makers to disguise high prices by passing them on to insurers. In response to the increasing public clamor, some drug companies looking for a scapegoat began blaming “the middleman.”⁴ The middleman is an old boogeyman. If a retailer wants to convince consumers its products are cheaper than competitors, it often claims “we’ve cut out the middleman.” However, the term “middleman” does not apply to the drug supply chain the way it did historically in consumer markets.

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Drug Material Suppliers. The drug supply chain starts with the makers of raw ingredients and includes drug makers themselves, drug wholesalers and pharmacies. Common sense suggests that the purveyors of raw ingredients, drug makers, wholesalers and pharmacies all want to charge prices as high as possible. Competition among the firms that make up the supply chain usually keeps excessive price hikes in check.

A scarcity of raw materials can sometimes increase drug prices. Even if multiple manufacturers produce a certain drug, there may be only one or two suppliers of the necessary raw materials.⁵ About 40 percent of finished drugs come from abroad, but about 80 percent of raw pharmaceutical materials are derived from foreign sources.⁶ 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.⁷

Drug Wholesalers. Drug wholesalers and distributors are arguably middlemen that raise prices. The wholesale drug industry has undergone tremendous market consolidation in the past few decades. Today, three large firms control nearly 90 percent of wholesale drug distribution.⁸ Having only a handful of large distributors potentially allows them to structure the market to their advantage.

Drug Retailers. Drugstores stand to both benefit and suffer when drug makers raise prices. Short-term profits could be squeezed, but long-term profit margins are likely to rise due to higher prices per script.⁹ One development that could harm consumers is consolidation among chain drugstores. Measured by revenue, the top five drugstore chains control nearly two-thirds of the retail drug market.¹⁰

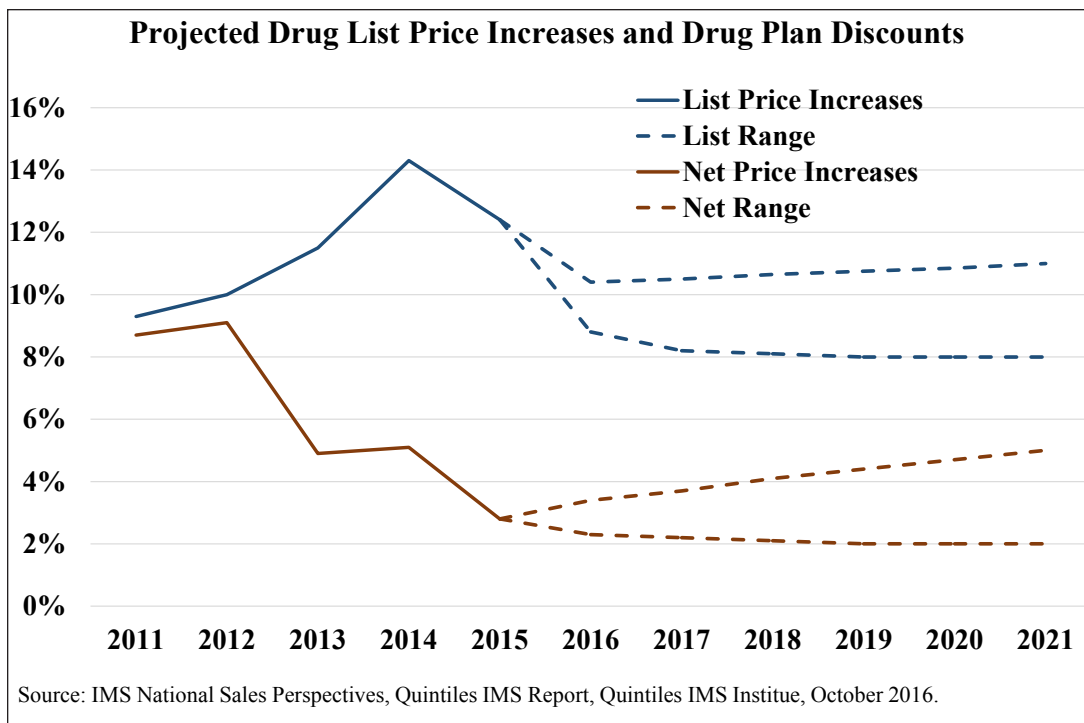
Retail pharmacies obviously must markup wholesale drug prices in order to earn a profit and stay in business. Yet, some drug makers cut out traditional retail pharmacies in an attempt to charge higher prices. Drug makers who have expensive name-brand products that have low-cost competitors sometimes contract with so-called “captured” pharmacies, with exclusive rights to dispense a given drug. This strategy is sometimes used to prevent retail drugstores from

substituting a cheaper generic alternative for a higher-priced drug. Captured pharmacies earn larger profits per script than they would from substituting generic drugs.

Drug Plans. Some drug makers have recently begun blaming high drug prices on pharmaceutical benefit managers (PBMs).¹¹ PBMs are not middlemen in the traditional sense; they are drug plan administrators. Insurers and employers hire PBMs to manage drug benefits and adjudicate drug claims for plan members. PBMs provide value using their purchasing power to leverage better prices. With multiple clients, large national PBMs can negotiate lower prices from manufacturers, and therefore possess far more bargaining power than individual firms. PBMs clients are employers, insurers, state Medicaid programs and Medicare Part D drug plans — not drug makers. Drug plans bargain for lower drug prices for their clients, which occasionally makes them unpopular with drug makers and pharmacy owners.

As the figure illustrates, only a fraction of drug-makers’ annual list price increases impact consumers after their drug plans negotiate a better deal on their behalf. Over the next five years, annual price increases for drugs are expected to average 8 percent to 11 percent. Yet the net price increase is expected to reach only 2 percent to 5 percent — a six percentage-point discount.

PBMs use a variety of techniques to control costs for health plans and drug plan members. 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.

Today, most Americans belong to a drug plan that manages drug benefits on their behalf. The ultimate buyers for 84 percent of all prescription drugs are insurers, employers and PBMs. Patients themselves pay for only about 16 percent of drugs out of pocket. According to industry data:

- Nearly one-fourth of retail prescriptions are fully covered by insurers and require no copayment by the patient.
- An additional one-third cost the patient \$5 or less.
- Just over three-fourths cost the patient \$10 or less.

Few people pay more than a nominal charge. Those who do often prefer name-brand drugs or are taking a drug not yet available in generic form. Thus:

- Less than 8 percent of prescriptions require a copay of more than \$30.
- Just over 2 percent of prescriptions require copays of \$70 or above.

Conclusion. To a significant degree, over-priced drugs are a problem exacerbated by the regulatory regime at the U.S. Food and Drug Administration (FDA), coupled with a lack of guidance from Congress. One way to rein-in high drug prices is to inject more competition into the drug market. Costly drugs would face numerous competitors if it did not require \$1 billion or more, on average, to bring new products to market. With more competition, it would be difficult for drug makers to maintain high prices.

The 21st Century Cures Act, signed by president Obama in December 2016, aims to streamline the approval process for new drugs. It allows the FDA to consider aggregate anecdotal data as evidence and take patient experiences into account, rather than being limited to rigid and costly double-blind clinical trials. However, the *Cures Act* will likely fall short of what needs to be done to streamline the drug approval process.

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Notes

1. The Health Strategies Consultancy LLC, “Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain,” Kaiser Family Foundation, Publication No. 7296, March 2005.
2. Devon Herrick, “How Federal Regulations Hiked EpiPen Prices,” National Center for Policy Analysis, Backgrounder No. 186, October 24, 2016.
3. Murray Aitken, Michael Kleinrock, Jennifer Lyle, Deanna Nass and Lauren Caskey, “Medicine Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014,” IMS Institute for Healthcare Informatics, April 2015.
4. Joseph Walker, “Drug Makers Point Finger at Middlemen for Rising Drug Prices,” *Wall Street Journal*, October 3, 2016.
5. C. Lee Ventola, “The Drug Shortage Crisis in the United States: Causes, Impact, and Management Strategies,” *Pharmacy & Therapeutics*, Vol. 36, No. 11, November 2011, pages 740-742 and 749-757.
6. Mari Serebrov, “Solutions Needed to Protect The U.S. Drug Supply Chain,” *BioWorld Today*, Sept. 15, 2011.
7. Erin P. Fox et al., “ASHP guidelines on managing drug product shortages in hospitals and health systems,” *American Journal of Health-System Pharmacy*, Vol. 66, 2009, pages 1,399–1,406.
8. “2014 Market Leaders: Top Pharmaceuticals Distributors,” *Modern Distribution Management*, 2015. Available at http://www.mdm.com/2014_pharmaceuticals_mdm-market-leaders.
9. Adam J. Fein, “Winners and Losers from Generic Drug Inflation,” *Drug Channels*, August 13, 2014.
10. Data attributed to Adam J. Fein, *Drug Channels*. Cited in Paul Ziobro, “Why Target Can’t Compete in Drugs,” *Wall Street Journal*, June 16, 2015. Available at <http://blogs.wsj.com/corporate-intelligence/2015/06/16/why-target-cant-compete-in-drugs/>.
11. Joseph Walker, “Drug Makers Point Finger at Middlemen for Rising Drug Prices,” *Wall Street Journal*, October 3, 2016.

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Recent NCPA Health Care Research Publications

Devon Herrick, “How to Make New Drugs More Affordable,” National Center for Policy Analysis, Issue Brief No. 203, January 5, 2017. - <http://www.ncpa.org/pub/how-to-make-new-drugs-more-affordable>

Patients are more sensitive to rising costs due to increasing deductibles and, because consumers pay more of their drug costs, pharmaceutical companies are less able to pass on high prices without anyone noticing.

Devon Herrick, “Capping Copays Will Raise Premiums and Drug Prices,” National Center for Policy Analysis, Policy Report No. 387, September 2016. - <http://www.ncpa.org/pub/capping-copays-will-raise-premiums-and-drug-prices>

State and federal proposals to cap drug cost-sharing would benefit a small number of patients with high drug costs, but could lead to higher drug prices and health insurance premiums for other patients by discouraging the use of generic alternatives to higher priced name-brand drugs.

John R. Graham, “The “Doc Fix” Is In: An Initial Assessment of Medicare’s New Rule over the Practice of Medicine,” National Center for Policy Analysis, Policy Report No. 386, July 20, 2016. - <http://www.ncpa.org/pub/the-doc-fix-is-in-an-initial-assessment-of-medicare-s-new-rule-over-the-practice-of-medicine>

In March 2015, an overwhelming bipartisan majority in Congress voted for the Medicare Access and CHIP Reauthorization Act (MACRA). The so-called “doc fix,” a component of MACRA, was an attempt to fix the very flawed method Medicare uses to pay doctors and other health professionals. Unfortunately, MACRA is fiscally irresponsible and increases the federal government’s control over how clinicians practice medicine.

Devon Herrick, “E-Prescribing: A Commonsense Solution to Opioid Abuse that Is Being Ignored,” National Center for Policy Analysis, Policy Report No. 385, July 8, 2016. - <http://www.ncpa.org/pub/e-prescribing-a-commonsense-solution-to-opioid-abuse-that-is-being-ignored>

Congress has taken up the growing problem of opioid abuse. Yet for all the talk there appears to be little discussion of a commonsense solution: mandatory electronic prescribing (e-prescribing).

Devon Herrick, “A Bogus Solution for High Drug Costs,” National Center for Policy Analysis, Issue Brief No. 194, June 21, 2016. - <http://www.ncpa.org/pub/a-bogus-solution-for-high-drug-costs>

Lately, a few politicians (and lobbyists for pharmacies and drug makers) have been attempting to divert some of the blame for high drug prices to the administrators of employee drug plans. They worry that pharmacy benefit managers (PBMs) mark up drug prices well above the PBMs’ costs or fail to pass along manufacturers’ drug rebates and other discounts to their clients (employers and insurers) and consumers with drug plans. The blame-shifters have suggested that employers and their workers could potentially benefit if PBMs were forced to disclose the (net) wholesale prices they paid for drugs. Economists, the U.S. Federal Trade Commission (FTC) and even the actuarial consulting firm Milliman, Inc. are rather skeptical of this argument.

Andrew J. Rettenmaier and Thomas R. Saving, “How to Pay for Medicare,” National Center for Policy Analysis, Policy Report No. 384, May 31, 2016. - <http://www.ncpa.org/pub/how-to-pay-for-medicare>

Medicare now provides insurance coverage for over 50 million Americans, and accounts for 20 percent of health care spending. One of the goals of the Affordable Care Act and of the majority of Medicare reform proposals has been to reduce or eliminate excess cost growth as it applies to federal spending. Without significant changes in the current program, it is not realistic to think that federal Medicare spending per capita can be constrained to grow at the same rate as per capita GDP.

Devon Herrick, “Congressional Brief: NCPA Health Reform Agenda,” National Center for Policy Analysis, May 11, 2016. - <http://www.ncpa.org/pub/congressional-brief-ncpa-health-reform-agenda>

Health reform must replace Obamacare with increased flexibility in health plan design; tax fairness regardless of where Americans get their health coverage; increased access to primary care by removing barriers to innovative medical practices and services; reform of hospital regulation to better serve patients; reduced costs through price transparency to boost competition and innovation in medical services and prescription drugs; strengthened Medicare, Medicaid and Veterans Health that better serve the needs of patients; and changes in the financing of medical care so that individuals have control over their health care dollars and the means to pay for medical care over their lifetimes.