



EXECUTIVE SUMMARY

Why Drug Pricing Reform Is Complicated: A Primer and Policy Guide to Pharmaceutical Prices in the US

by Craig Garthwaite and Amanda Starc

NOVEMBER 2023

Introduction

Pharmaceutical drug pricing processes in the United States are complicated and opaque. As a result, reforms intended to reduce drug prices may readily wind up being ineffective; they may even cause harm by decreasing society's access to innovative new treatments. Ultimately, drug pricing policy involves a tradeoff: allowing relatively high prices (compared to other countries) today provides firms with the incentive to make the large, fixed, and sunk investments necessary to bring future new products to market. For this reason, high prices are a central part of the process by which Americans gain access to new drugs. However, some firms may take advantage of the system's complexity to extract profits at a rate that far exceeds any beneficial incentive effects. Craig Garthwaite and Amanda Starc explain the underlying complexities of how prices are set and suggest areas where policy reforms could improve market competition and efficiencies, thereby reducing drug prices without discouraging therapeutic innovation.

The Core Trade-Off in US Drug Pricing

In the United States, prescription drugs are often sold at orders of magnitude over their marginal cost of production. This phenomenon often sparks frequent and heated debate, with high drug prices sometimes attributed exclusively to unmitigated corporate greed. However, Garthwaite and Starc argue that high US pharmaceutical prices are not a mystery, mistake, or accident; nor are they the obvious result of greed.

Rather, high prices are a deliberate feature of the complex system by which new products are brought from the scientific bench to the patient's bedside. The total cost of developing and demonstrating the safety and efficacy of potential new drugs involves large investments in research and development. Only around 10 percent of products that enter clinical trials in humans make it to the market, many more targets fail long before they ever make it into human trials.

The authors posit that society's goal should not be simply to lower prices but instead to increase value. While the need to attract and incentivize investment implies the need for a degree of price setting above marginal cost, the optimal policy is not one that allows unbounded markup. Pricing reform should address market failures and other features of the pharmaceutical value chain that increase prices without increasing value.

A Primer on Pharmaceutical Prices

A key feature of the pharmaceutical sector is that most purchasers of pharmaceuticals are insured customers. This state of affairs weakens the relationship between the prices manufacturers charge and the demand for their products.

Pharmaceutical markets feature three broad categories of economically important prices: (1) the public list price, similar to the sticker price at a car dealer that is the starting point for negotiation; (2) the net price actually paid by a plan sponsor or government insurer, which is negotiated by a pharmacy benefit manager (PBM) or dictated by regulation; and (3) out-of-pocket payments from consumers. The second and third prices are determined primarily along three dimensions: (1) how many other products exist that treat the same medical condition; (2) whether the product is purchased in a retail setting or administered by a medical provider; and (3) who is paying for the product.

Understanding the relative importance of these features of the price-setting process requires context about the distribution of pharmaceutical spending. To give some scope for understanding pharmaceutical prices, Garthwaite and Starc explain how the context for price setting differs across four categories of pharmaceutical products:

Retail vs. Non-Retail Pharmaceuticals

Whether pharmaceutical products are purchased by a patient at a retail location or administered by a medical provider in an outpatient setting dictates the relevant price-setting process. In recent years the share of pharmaceutical spending in physician-administered settings has increased, largely because of the development of specialty products, which are generally more expensive products that treat more serious conditions and often require special handling or administration. The prices for these physician-administered drugs (PADs) are negotiated by medical providers with wholesalers rather than by PBMs.

Small-Molecule vs. Large-Molecule Products

Scientific advances have allowed for the development of new types of large-molecule or biologic products, which are typically grown rather than manufactured, a process that results in much higher marginal costs. Pharmaceutical spending on large-molecule products grew by nearly 25 percent from 2014 to 2017, and these biologic products now account for approximately 40 percent of all FDA approvals each year.

Branded vs. Generic Products

Though estimates reveal that only 20 percent of prescriptions are for branded drugs, over 80 percent of drug spending is on branded drugs, because they are meaningfully more expensive than their generic counterparts. Generics lower prices for a number of reasons, including that their manufacturers lack the monopoly-pricing power of branded manufacturers, insurers steer consumers toward generics through formulary design, and many states require automatic substitution of generics. However, drug shortages are increasingly commonplace for generic drugs. Furthermore, alleged

anticompetitive behavior has also led some generics' prices to skyrocket. The market becomes more attractive to entrants to discipline pharmaceutical cartels following price hikes, but overall, the structure of the generics market generates low returns to both entry and investment in quality.

Payer Type

An important feature determining pricing is whether the payer involved in a purchase is Medicare, Medicaid, or the commercial segment. In each of these segments, prices vary across the dimensions discussed above. But prices also vary within those categories based on payer type. Medicare Part D, which provides retail prescription-drug coverage for the elderly and disabled, is primarily financed by the federal government, but most of its negotiation and administration are handled by private firms. Research shows that products with a higher share of patients on Medicare had greater list-price growth, as manufacturers and Part D plans attempted to shift spending onto patients and the government. State Medicaid programs pay the lowest or "best" price in the market by regulation. Effectively, this regulation means that manufacturers who give large discounts to commercial payers must then give similar discounts to Medicaid.

Another important feature of this complicated market is the way prescription drugs move from manufacturers to patients. Garthwaite and Starc explain that the path of a product from a manufacturer to the patient starts with patent-holding manufacturers selling branded products largely to wholesalers at a small discount. Wholesalers then sell branded products to pharmacies at a price similar to their cost of acquisition; pharmacies then sell directly to patients. The pharmacy market has become increasingly concentrated and larger pharmacies have more leverage in negotiations with wholesalers and buyers than smaller independent pharmacies do. Over time, pharmacy benefit managers (PBMs) of insurance plans have moved into owning specialty pharmacies and requiring enrollees to use them rather than independent providers.

The actual prices paid for retail pharmaceuticals are largely determined by negotiations between PBMs and manufacturers or by regulation. Rebates negotiated by PBMs grew from \$43 billion in 2007 to \$223 billion in 2022. This growth reflects in part the ability of PBMs to credibly promise to move market share to alternative products, including by their use of formularies that dictate what drugs patients may access.

Patient cost-sharing comes mainly in the form of deductibles, co-payments, and coinsurance. There is little evidence that patients respond to high cost-sharing in a well-informed manner; they appear to stop taking nearly all drugs when faced with higher out-of-pocket expenses.

Policymakers' general view is that PBMs are exploiting their position as middlemen to siphon money from both patients and pharmaceutical firms, but the authors observe that it is not clear whether this view is accurate. Plan sponsors concerned about PBMs manipulating prices can move their contracts to other PBMs. However, such movement is made more difficult by the fact that the three largest PBMs now represent over 80 percent of the market, and the four largest PBMs are wholly owned by large national insurance firms. In addition, the lack of transparency around rebates creates concerns as to whether the administrative fees associated with them represent bona fide services or are instead simply a renamed version of rebates that are designed to allow PBMs to take advantage of asymmetric information to capture more value from the supply chain.

Where the US Drug Pricing System Can Be Improved

Concern about the high and rising prices of prescription drugs has led to legislative and policy activity including the passage of the 2022 Inflation Reduction Act (IRA), which allowed Medicare to negotiate certain drug prices for the first time. Garthwaite and Starc state that the evidence is clear that such legislation will reduce the level of investment in new products and the pace of new biopharmaceutical-product entry.

However, the authors are clear that this state of affairs is not a reason for policymakers not to address the issue of drug pricing. Rather, they suggest that the optimal policy requires a focus on identifying areas where existing systems for acquiring or purchasing drugs and/or financing their purchase are causing unnecessary inefficiencies that decrease access to products today without providing sufficient incentives for firms to invest in future innovation.

Implementing Price Negotiation in Medicare Part B

Garthwaite and Starc note that as part of the IRA, Medicare will now have a more direct hand in setting prices for the most expensive drugs in the Medicare program. Many policymakers and health policy experts have concerns that the PADs covered by Medicare Part B face less stringent negotiations than those covered now by Part D. And Part B's "buy and bill" system, though intended to provide doctors with simplicity and predictable reimbursement, also increases prices for public and private markets while potentially shifting market share to more-expensive treatment options as well.

The authors argue that any successful reform must attract physicians and other providers into the system while remaining attractive enough to vendors to induce new market entrants, and that policymakers should adopt more of a vendor model for distribution of PADs. Such a model would take away most of physicians' current incentive to prescribe particular medications.

Promoting Small-Market Generic Competition

Promoting competition in generics would likely produce substantial gains for consumers because generics are produced in such large quantities. The authors state that reducing barriers to entry is especially important in this market to overcome cartelized markets and high costs and long delays before beginning production. In addition, small product markets may simply be unable to support more firms; for firms to charge high prices without fear of competitor entry in small generic markets is now widespread throughout the industry. Solutions to this problem will need to come either from firms being harmed by this practice or through government action.

To lower fixed entry costs, the authors suggest the FDA continue efforts to find efficiencies in the process for approving new drugs. Other potential solutions include (a) aggregating demand across developed countries to increase the size of some generic markets, and (b) empowering the FDA to provide a new form of market exclusivity for generics with market sizes that do not support multiple competitors. Further, additional funding for regulatory agencies would help them ensure generic-product quality and to consider more careful oversight and monitoring of rebate contracts that reference rivals.

Addressing Potentially Excessive Cost Sharing and the Value of Insurance

The authors write that US drug markets have seen higher cost sharing for some of the most expensive medications. Co-payment assistance and coupon programs implemented by pharmaceutical companies in response to this issue have been shown to increase overall drug spending. One possible way policymakers could address these issues would be to create upper limits on both the amount of cost sharing that can be charged to consumers and co-payment assistance in the commercial market.

Improving the Flow of Information between PBMs and Plan Sponsors

Garthwaite and Starc state that the current system of confidential rebates and other payments between manufacturers and PBMs creates an incentive for a PBM to give preference to a higher-list-price drug that offers greater rebates or other fees—even if it has a higher net price for the plan sponsor. This state of affairs reflects a fundamental question about the amount of competition in the market for PBM services. Even in cases where PBMs are earning excess profit, new competitors are unlikely to successfully enter the market if there are large barriers to entry, perhaps because large scale is necessary for competition. Strong competition is less likely to emerge given that plan sponsors are unaware of the full scope of surplus created by their prescriptions.

The authors argue that it would be unwise to limit the ability of PBMs to negotiate large discounts and that instead, policymakers should move to a system where all payments between manufacturers and PBMs flow first to payers before being split with PBMs. Negotiations between PBMs and payers would then occur between two parties with equal information about the amount of money at stake. To effect such a system, regulators could end the safe harbor for payments between manufacturers and PBMs and create a separate safe harbor for payments between manufacturers and payers.

Increased Pharmacy Competition

Despite greater concentration in the retail pharmacy market, consumers are fairly willing to switch pharmacies. However, the balance between buyers and sellers is fragile, especially given barriers to entry, and this fragility provides the possibility of tacit collusion.

The authors recommend that policymakers continue to encourage the use of generics, particularly in government programs that traditionally do less steering of consumers. They should also encourage competition among retail pharmacies, such as by advocating for the adoption of preferred-pharmacy networks that encourage consumers to fill their prescriptions at locations with the lowest prices.

Conclusion

The approach of the Inflation Reduction Act and other proposed drug-pricing policies primarily reflects society's frustration over high pharmaceutical prices, rather than signaling an evidence-based approach to drug pricing reform. Garthwaite and Starc claim that these reforms fail to address the reality that higher prices are a deliberate feature of the complex system through which new products are brought from the scientific bench to the patient's bedside. To develop a system that maximizes social welfare, policymakers should focus not simply on lowering prices but instead on increasing overall value. By identifying instances in which profits are likely to exceed the level necessary to generate socially efficient investments, policymakers can increase the value the pharmaceutical system creates as well as the proportion of that value captured by patients.

ABOUT THE AUTHORS

Craig Garthwaite

Herman R. Smith Research Professor in Hospital And Health Services, Kellogg School of Management

Craig Garthwaite is the Herman R. Smith Research Professor in Hospital and Health Services, a professor of strategy, and the director of the program on health care at Kellogg (HCAK). He is an applied economist whose research examines the business of health care with a focus on the interaction between private firms and public policies. His recent work in the payer and provider sectors has focused on the private sector effects of the Affordable Care Act, the impact and operation of Medicaid Managed Care plans, the responses of nonprofit hospitals to financial shocks, and the economic effects of expanded social insurance programs such as Medicaid and Medicare for All. Professor Garthwaite also studies questions of pricing and innovation in the biopharmaceutical sector. In this area he has examined the effect of changes in market size of investments in new product development, the evolving world of precision medicine, expanded patent protection on pricing in the Indian pharmaceutical market, the innovation response of United States pharmaceutical firms to increases in demand, and the relationship between health insurance expansions and high drug prices. His research has appeared in journals such as the Quarterly Journal of Economics, the American Economic Review, the Annals of Internal Medicine, and the New England Journal of Medicine. Garthwaite received a BA and a master's in public policy from the University of Michigan and his PhD in Economics from the University of Maryland. Prior to receiving his PhD, he served in a variety of public policy positions including the director of research for the Employment Policies Institute. He has testified before the United States Senate, United States House of Representatives, and state legislatures on matters related to the health care markets, prescription drugs, the minimum wage, and health care reforms.

Amanda Starc

Associate Professor, Kellogg School of Management, Northwestern

Amanda Starc, PhD, is an associate professor of strategy at the Kellogg School of Management and a research associate at the National Bureau of Economic Research (NBER). She received her BA in Economics from Case Western Reserve University, and her PhD in Business Economics from Harvard University. Dr. Starc's research agenda sits at the intersection of industrial organization and health economics. Her research spans three main themes. First, she studies the fundamental economic question of what health insurance covers and how it is priced. Second, she studies how information shapes consumer demand for both insurance and health care. Finally, she studies the efficacy of market mechanisms in allocating goods and services in health care markets.

About the Aspen Economic Strategy Group

The Aspen Economic Strategy Group (AESG), a program of the Aspen Institute, is composed of a diverse, bipartisan group of distinguished leaders and thinkers with the goal of promoting evidence-based solutions to significant U.S. economic challenges. Co-chaired by Henry M. Paulson, Jr. and Timothy F. Geithner, the AESG fosters the exchange of economic policy ideas and seeks to clarify the lines of debate on emerging economic issues while promoting bipartisan relationship-building among current and future generations of policy leaders in Washington.