PRI CENTER FOR MEDICAL ECONOMICS AND INNOVATION

COVERAGE DENIED

ISSUE BRIEF PART SIX

Promoting Transparency and Competition in the Drug Market

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Executive Summary

In addition to the reforms to the health insurance system, which will help address the problems of drug affordability, reforms tailored to the pharmaceutical sector are necessary. These reforms should eliminate drug supply chain inefficiencies and include:

- fostering a patient-controlled generics market,
- creating price transparency through reforms that ensure patients directly benefit from all discounts when purchasing their medicines,
- fixing the drug formularies' systemic biases against low-cost medicines, and
- encouraging contracting innovations that could create more innovative ways for pricing medicines.

Part 3 of the Coverage Denied series documented how the flawed health insurance model is a prime driver of the drug affordability crisis. The reforms discussed in Part 5, which empower patients in the health insurance markets, will address many of the disincentives driving these problems.

Achieving the twin goals of promoting robust pharmaceutical innovation and widespread drug affordability requires additional reforms, however. These reforms should explicitly remove the disincentives embedded in the current drug supply chain that are also important drivers of the drug affordability problem that too many patients face.

Drug Policy Should Promote Innovation and Affordability

Simultaneously promoting innovation and drug affordability requires a careful balancing act because these goals can contradict one another. Drug affordability requires robust competition to drive down costs, but incenting innovation requires market exclusivity to provide innovators with an opportunity to recover their cost of capital.

The capital costs for developing a new medicine are high because drug development is a long and risky process. It takes an average of 12 years or longer for a new drug to gain FDA approval once a biological target has been identified.[1] Years of research does not guarantee success either. Failure is not just a possibility; it is the norm. Overall, "the likelihood that a drug entering clinical testing will eventually be approved is estimated to be less than 12 percent."[2] Consequently, the capitalized costs to develop a new therapy are estimated to be $2.6 billion according to DiMasi et. al. (2016). Including the required post-approval expenditures, the capitalized costs increase to $2.9 billion.[3]

Incentivizing the development of innovative medicines requires prices for innovative products to reflect the capital costs for creating a drug. If competitors that have not incurred the expensive development costs were allowed to immediately compete with the innovators, these new entrants could undercut the innovators' more expensive price that must reflect the costs of manufacturing and innovation.[4]

In such an environment, innovators would be unable to recoup their capital costs and the result would be lost innovation. Our capacity to treat diseases like Alzheimer's, cancer, or even the coronavirus would be compromised, worsening our healthcare outcomes, and ironically, increasing our systemic healthcare costs.

Higher healthcare spending would follow because research has demonstrated that greater pharmaceutical use is linked to lower overall healthcare spending. For instance, the Congressional Budget Office (CBO) estimates that "a 1 percent increase in the number of prescriptions filled by beneficiaries would cause Medicare's spending on medical services [a much larger expenditure category] to fall by roughly one-fifth of 1 percent."[5] Spending more money on innovative drugs can reduce total healthcare spending because the use of drugs often reduces the need for other more expensive services like hospital stays and surgeries.

An efficient patent process creates a period of exclusivity, which has been around 12 years in practice. This exclusivity gives innovators the opportunity to recoup their capital costs and incentivizes innovation. To promote affordability, robust competition needs to be incentivized once the exclusivity period has expired. For years, the process of a set exclusivity period to encourage innovation followed by a robustly competitive drug market to improve affordability has enabled both goals.

From an innovation perspective, the U.S. is the leader in developing new medicines. According to Friedman (2017), "North America (largely the United States) accounts for more than half of the drug patent inventorship, European nations account for one-third of the inventors, and Asian countries account for just over 7 percent."[6] Further, as the CBO noted,

- In 2019, the pharmaceutical industry spent $83 billion dollars on R&D. Adjusted for inflation, that amount is about 10 times what the industry spent per year in the 1980s.

- Between 2010 and 2019, the number of new drugs approved for sale increased by 60 percent compared with the previous decade, with a peak of 59 new drugs approved in 2018.[7]

Enabling a competitive environment to flourish once an innovative drug's exclusivity expires has promoted broad-based affordability as well. Generic and biosimilar competitors now account for 90 percent of all prescriptions dispensed.[8] The average copay for a generic drug was $6.61 in 2021 and 93 percent of all generics had a copay less than $20.[9]

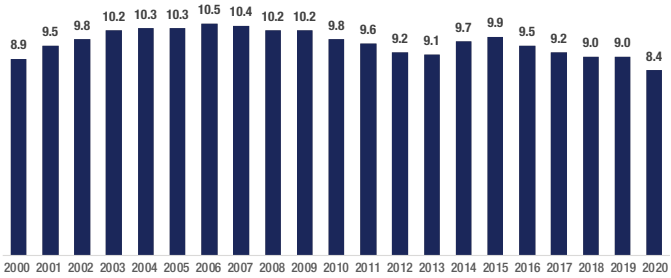
Affordability Is an Insurance-Design Issue Impacting a Minority of Drugs

The widespread availability of affordable drugs indicates that drug affordability is a problem for specific high-cost medicines and elderly patients who require many medications that must be taken every day. This problem is created by the failings of the drug supply chain and the inability of the insurance system to efficiently cover the risks associated with requiring expensive medicines.

The quest for greater affordability encourages too many policymakers to advocate for price controls, such as the misnamed Inflation Reduction Act (the bill will aggravate – not alleviate – inflation), which was signed into law by President Biden in August 2022 and gives Medicare the right to "negotiate drug prices". Since the negotiations are backed up by a threat to impose a 95 percent tax on the nonconforming company's revenues (not profits), the bill effectively implements price controls.[10] Price controls undermine the purpose of the current patent system. If it spreads, these policies will make it nearly impossible for most innovators to cover their capital costs. They are not the answer.

Unlike price controls, effective policies correctly diagnose the nature of the drug affordability problems that afflict patients and establish reforms that address these causal factors. Starting with what it is not, the drug affordability problem is not a pricing issue. This reality is demonstrated by the fact that total drug expenditures have remained around 10 percent of total national health expenditures for the last twenty-years, see Figure 1.

FIGURE 1
PRESCRIPTION DRUG EXPENDITURES PERCENTAGE OF NATIONAL HEALTH EXPENDITURES 2000 - 2020



Source: CMS

While total drug expenditures are growing in line with overall healthcare costs, it is a different story for patients. The patient's share of the costs depends on their specific deductibles (the amount a patient pays before insurance kicks-in), co-pays (a fixed dollar cost), and co-insurance rates (the patient's percentage share of the costs). The share of costs that patients are being required to cover are growing because their deductibles and co-insurance costs are rising as a share of total net drug spending.

Therefore, at its core, the drug affordability issue is a problem of patients being required to cover an excessive amount of the financial risks from needing expensive medicines through high out-of-pocket requirements. The flaws in health insurance coupled with the flaws in the drug supply chain inequitably shift costs on to patients, which is the major driver of the affordability problem.

This inequitable cost shift begins with the problem of fast-growing list prices, but slow-growing net prices – a phenomenon designated as the "gross-to-net bubble"

by Drug Channels.[11] While the fast-growing list prices do not create an affordability problem for the healthcare system, as demonstrated in Figure 1, it hurts patients with high co-insurance rates, because co-insurance rates are generally based on list prices.

Thus, as list prices have been growing rapidly (particularly the list prices for expensive medicines), patients' costs have been rising. Consequently, patients who take expensive medicines are experiencing growing affordability problems even though the net costs of drugs are not increasing. The combination of problems created by the gross-to-net-bubble with the prescription drug escalator – the fact that patients take more and more medicines as they get older, as discussed in Part 3 – drives the exceptionally large affordability problem some patients face. Fixing the risk from unaffordable out-of-pocket costs for drugs requires addressing the current third-party payer insurance system (as discussed in Part 5) and reforms that eliminate the disincentives that plague the broader drug supply chain.

Reforms Should Foster a Patient-Controlled Generics Market

Just as with broader healthcare expenditures, the ineffective health insurance system distorts the drug market to the detriment of patients. One fundamental flaw that drives these disincentives is the inclusion of generic medicines under current health insurance prescription drug plans. As the Kaiser Family Foundation's (KFF) annual Employer Health Benefits Survey noted,

> The large majority of covered workers (92%) are in a plan with tiered cost sharing for prescription drugs. Cost-sharing tiers generally refer to a health plan placing a drug on a formulary or preferred drug list that classifies drugs into categories that are subject to different cost sharing or management. It is common for there to be different tiers for generic, preferred and non-preferred drugs, and in recent years, plans have created additional tiers that may, for example, be used for specialty drugs or expensive drugs such as biologics.[12]

The KFF survey demonstrates that most employer sponsored health insurance contains multiple tiers, including a tier that covers generic medicines. However, by incorporating expenditures that are not a financial risk into the health insurance systems, the financing system is harming patients. One of those adverse impacts is higher costs for patients. As a recent study by the USC Schaefer Center for Health Policy & Economics demonstrated,

> growing evidence indicates U.S. consumers and employers and the government often overpay for generics as pharmacy benefit managers (PBMs) and their affiliated insurer companies game opaque and arcane pricing practices to pad profits. PBMs played an essential early role in driving U.S. uptake of generics. However, PBMs' current practices—coupled with market distortions within the pharmaceutical supply chain—have inflated retail generic prices. Commercial tactics such as spread pricing, copay clawbacks and formularies that advantage branded drugs over less expensive generics have funneled the savings from low-cost generics into intermediaries' pockets, rather than the pockets of patients.[13]

Beyond unnecessarily raising costs for patients, turning a non-insurable transaction into an insurable one creates the same problems in the drug market as it does in the broader healthcare system. Patients are no longer in control of how their money is spent and pharmacies must serve the needs of insurers, not just patients. However, requiring a generic medication is not a financial risk for the vast majority of patients.

Since the need to take generic medications does not create large financial risks, patients serve as

more effective consumers when purchasing their own generic medicines than do insurers. On the supply-side, the entry of market disruptors such as Amazon Pharmacy and Wal-Mart illustrate that pharmacies are well positioned to leverage cutting-edge technologies to directly provide patients access to cheap and affordable generics.

Freeing generics from the complexities of the health insurance system enables the creation of a more efficient generic market that, since 90 percent of all drugs sold are generic, promotes widespread drug affordability. Freeing generics from the complexities of the health insurance system also empowers patients to control the purchases of their generic medications and enables them to directly benefit from the savings generated by market disruptors. With patients able to find the best deals and market disruptors emboldened to provide those savings, the excessive expenditures on generics will decline and patients' out-of-pocket costs will go down.

However, there remains one obstacle to this beneficial outcome that also afflicts innovative medicines: drug pricing opacity.

Eliminate Drug Supply Chain Inefficiencies by Creating Price Transparency

Whether it is the low-cost generics market or high-valued innovator products, establishing a patient-driven pharmaceutical market requires a transparent price system that ensures patients understand medicines' actual prices inclusive of all discounts and rebates – the net prices. The benefit from price transparency is simple: It empowers patients. Understanding the actual price of the medicine incentivizes payers to pass all discounts along to the patients requiring expensive medicines rather than the current system where those discounts are pocketed by the intermediaries and then *partially* passed along to *all* patients through lower premiums. For generic medicines, transparent prices allow patients to find the low-cost medicines that best serves their needs.

Transparency also reveals the diverging incentives between PBMs and patients. Currently, fast rising gross prices (e.g., wholesale acquisition costs, WAC) and skyrocketing discounts serve PBMs well because such a pricing system earns PBMs more income and helps these organizations justify their services. Insurers also benefit because the savings they reap from the large discounts can lower overall premiums. However, this system penalizes patients because their out-of-pocket costs are based on the gross prices, meaning patients who require expensive medicines are not receiving their expected insurance services – they are bearing large financial costs from a healthcare risk (e.g., requiring an expensive medication) that properly functioning insurance services would cover.

Such a distorted insurance system can only thrive when prices are opaque. With price transparency, the current warped system where patients experiencing large financial risks subsidize the costs for everyone else would not persist. By revealing the consequences from these disincentives for all to see, a transparent pricing system fosters a healthier competitive market and aligns the compensation incentives of PBMs and payers with the needs of patients.

Currently, the opaque pricing environment thrives because the discounts negotiated by PBMs are considered proprietary data, and markets do not efficiently function without transparent prices. Therefore, promoting greater affordability requires policies that eliminate the current opaque pricing environment and establishes a transparent environment in its stead.

Reforming safe harbor protections for drug rebates, which was proposed in 2019, would yield immediate transparency benefits and directly reduce patients' out-of-pocket costs when they purchase their medicines.[14] The proposed reforms would have, effectively, ensured that all discounts paid by manufacturers must directly benefit patients (e.g., lowers their out-of-pocket spending) when purchasing their medicines. Patients directly benefit from this proposal because they would receive the large discounts and other rebates paid by manufacturers when purchasing their drugs. These discounts and rebates currently equal more than one-

half of the total revenues for branded drugs.[15] Thus, this proposal directly alleviates the untoward outcome of rising out-of-pocket expenditures but flat overall drug costs. Patients also benefit indirectly because the proposal helps to deflate the gross-to-net bubble, which promotes broad-based price transparency.

Requiring insurers to disclose to patients the current list prices as well as the current and historical net prices, known as "transparency in coverage" regulations, would enhance the benefits from reforming the safe harbor regulations.[16] Just as when consumers purchase any product outside of the healthcare sector, patients should be aware of the relevant pricing information when purchasing their medicines and the prices should be conveyed in an accurate, relevant, and understandable format.

Fix the Systemic Biases Against Low-Cost Medicines

The lack of transparency and control over the formularies by third-party payers rather than patients has also incented the use of higher-cost medicines (e.g., originator biologics) rather than lower-cost alternatives (e.g., biosimilars) in too many instances. Such benefit designs leave patients exposed to thousands of dollars in costs, which could be substantially lower if the system would encourage the use of the lower cost medicines.

The claim that prices are lower, and quality is higher, when consumers have more choices is typically uncontroversial. Yet for some reason this basic economic logic is lost when it comes to purchasing the medicines that patients need to live long healthy lives. The drug market is predicated on the theory that intermediaries (whether they are insurers, government or employer payers, or PBMs) can ensure better prices on medicines by restricting patients' choices.

On its face, this logic is absurd. Choice and competition drive improvements in quality and reductions in prices. Despite the irrationality, PBMs and insurers use the drug formulary – the list of approved medicines that detail which drugs are covered and under what terms – for this very purpose. Drugs are prioritized on the formulary to encourage the use of certain drugs; the drugs listed on worse formulary tiers receive inferior coverage, and patients will generally have no access to the drugs that are excluded from the formulary entirely.

Drugs listed on the most favored formulary tier do not necessarily offer patients the best combination of price and value, however. Take the coverage of biologic medicines as an example. Biologics are high value medicines that have improved outcomes for patients living with devastating diseases such as cancer and auto-immune disorders. Developing and producing these drugs is costly because these medicines are complex therapies derived from living organisms.

Competitors to originator biologics exist (i.e., biosimilars) that are just as clinically efficacious and 40 percent to 60 percent less expensive than the originators. However, far too many drug formularies place biosimilars on worse tiers or restrict physician and patient choice using biosimilar product exclusives in exchange for large rebates from the manufacturers. This denies patients the opportunity to use these medicines. As a result, the formulary restrictions reduce patient choice and force patients to pay higher costs.

The situation is even worse when drugs are excluded from the formulary altogether. According to a 2020 study by healthcare consulting firm Xcenda, this practice has been exploding, with the 3 PBMs that account for three-quarters of all prescriptions processed excluding "nearly a thousand prescription medicines" from their formularies since 2014.[17]

As Xcenda noted, many adverse consequences can result when formulary policies force hundreds of thousands of patients to switch from their current medications to their PBM's preferred drug. These costs are more severe for patients living with chronic diseases who must take their medicines continuously for a long time and include "worsening health outcomes and increased utilization of costly emergency and hospital care."[18] Promoting greater transparency and ensuring that patients benefit from all manufacturer discounts will

help address these inefficiencies harming patients.

While more abstract, the policy environment should encourage contracting innovations that could lead to more innovative ways for pricing medicines. For instance, Winegarden (2021) suggested that alternative contracting arrangements that created separate prices for innovation and production would create many benefits that include ensuring that patients have access to the most efficacious lowest cost medicine available.[19] These contracting reforms suggested that the prices that reflect a drug's innovation services (e.g., the capital costs associated with drug development) should be negotiated separately from the prices that reflect a drug's production services (e.g., physically producing and distributing the medicine). Specifically,

> a two-part pricing system is a contracting reform that can establish prices that separately reflect the value for medicines' innovation services and the value for medicines' production services. Under the two-part pricing system developed in this paper, the first price would be an access fee for innovative medicines, established via a negotiation between insurers and manufacturers. Insurers would pay the access fee on behalf of their beneficiaries. Once paid, the fee would ensure that all people covered by the insurance plan can access the drug and only need to cover the costs associated with the profitable production, transportation, and distribution of safe and efficacious medicines. These costs are much lower than the costs of innovation and are the second price of the two-part pricing model.[20]

The two-part pricing model exemplifies the notion that radically different approaches to pricing drugs can meaningfully improve the efficiency of the drug supply chain and eliminate many of the adverse consequences harming patients.

Conclusion

The goal of pharmaceutical regulations should be to improve the quality of healthcare by simultaneously promoting innovation and fostering wider affordability. Achieving these goals requires reforms that eliminate the disincentives that pervade the current drug market. First, the broader health insurance reforms outlined in Part 5 should include pharmaceuticals.

Second, additional reforms that improve the workings of the pharmaceutical market must be implemented. These reforms should:

- establish a patient-controlled market for low-cost generic medicines that, for most patients, does not involve insurers
- promote greater pricing transparency
- eliminate the loopholes that allow industry intermediaries to divert drug discounts to other parts of the healthcare ecosystem
- foster innovative contracting arrangements.

Endnotes

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