Q&A: The legal drug crisis in the US

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Credit: AI-generated image (disclaimer)

Three out of four American adults say prescription drug prices are unaffordable, and nearly a third admit to not taking prescribed medications due to cost, according to a recent poll conducted by the Kaiser Family Foundation. The foundation's data confirmed that Americans have a higher out-of-pocket cost for drugs than comparable nations.

A law signed a year ago, but being held up by legal challenges, is an attempt to lower drug prices. The law gave Medicare—the federal insurance provider for those over 65 and those under 65 with certain disabilities—the power to negotiate prices with pharmaceutical drug manufacturers on certain costly drugs.

While the law focuses on a segment of the branded pharmaceutical market, the generic drug market faces serious shortages and quality problems. More than 100 pharmaceutical drugs are in short supply, among them critical cancer drugs, medication for treating attention deficit disorder and certain commonly used antibiotics.

Kevin Schulman, MD, professor of medicine at Stanford and director of the Clinical Excellence Research Center, has published often on the topic. He recently spoke about why U.S. drug prices are so high, why there is a shortage of some medications and how to fix problems within the Medicare system.

Why does the US have such high drug prices?

It starts with the fact that pharmaceutical companies set their own prices. We don't have a centralized purchaser like in other markets, such as the U.K. and other countries in Europe, and we have a tremendous lack of transparency across the entirety of the payment model. Rather than a market where pharmaceutical companies compete on the basis of list prices, our market sets high list prices for drugs at the pharmacy, but then funnels back enormous amounts of money from pharmaceutical companies to intermediaries in the form of rebates and other payments. As these payments have grown, list prices have seen double-digit increases for consumers. Shockingly, none of us are told about these payments when we go to the pharmacy.

Why do other countries have lower drug prices?

In Europe, patients have access to most of the drugs we do at a fraction of the cost because they have nationalized pricing mechanisms and negotiate directly with drug manufacturers. American pharmaceutical companies argue that price negotiation discourages innovation, even though there's little evidence to support that argument. Most importantly, other countries also don't rely on intermediaries—otherwise known as pharmacy benefit managers—that control access and drive up drug prices in the U.S.

What are pharmacy benefit managers and how do they affect the pricing system?

Pharmacy benefit managers, or PBMs, are companies that work for health insurers to administer the prescription drug portion of employee health insurance plans. As intermediaries, PBMs negotiate drug prices and placement on the lists of drugs insurers agree to cover. PBMs then receive rebates and fees from the drug manufacturers for each unit of product sold, which results in higher drug prices for consumers. While PBMs work for employers, they also work for themselves, profiting in many ways from higher drug prices. All of these payment mechanisms are constructed under a veil of secrecy, and it's distorting drug pricing in the U.S. market.

What were the factors that led to the recent drug shortages, and how does the generic market figure into the equation?

Today, generics make up 90% of all medications used in the U.S. and provide enormous savings to consumers. Generics are drugs that are

chemically equivalent to brand-name drugs—they enter the market when the branded product loses intellectual property protection, typically after 20 years. The generic drug program was intended to provide a tremendous savings to consumers. But we have a generic market that's totally focused on price and not on product quality or supply chain quality.

Every time a manufacturer brings a new generic drug to the market it offers even lower prices, and that drives down prices for all manufacturers—sometimes even below the prices agreed to in signed contracts. Eventually, prices become so low that firms leave altogether, causing shortages. The problem of drug quality was compounded by the pandemic because it caused the U.S. Food and Drug Administration to fall behind on inspections of foreign factories, which provide 80% of the active ingredients in generics.

We often get low-price drugs from low-quality manufacturers. In the case of Intas Pharmaceuticals, a major manufacturer of the cancer drug cisplatin, FDA inspectors found enormous and systematic quality problems, and the product was removed from the U.S. market. In that way, a product-quality problem turned into a supply problem, because we didn't have enough alternative manufacturers for that drug.

How can we bring prices down and ensure shortages of essential drugs don't occur?

The simple answer is we have to reverse the economics behind drug shortages. We need to ensure a market price above the cost of producing it with good quality manufacturing. Consumers don't buy the lowest price products on Amazon irrespective of the quality ratings—but, essentially, this is how the generic drug market works. We need to identify and reward quality, even if quality results in marginally higher

prices for generic drugs. We want drug manufacturers to invest in quality products, and we want distributors to have robust supply chains. We also want purchasers like hospitals to recognize how a single focus on short-term price results in critical drug shortages over the long term.

CivicaRX, the not-for-profit drug maker, is an example of a good model of this solution. It addresses the instability of generic drug supplies by offering hospitals long-term contracts for medications at a price tied to manufacturer stability and quality. New data show that this strategy actually reduced costs over the long term.

When the Alzheimer's drug aducanumab led to one of the largest-ever price increases in Medicare Part B, you published a paper in *JAMA* with CERC colleague Barak Richman proposing a unique approach to reducing Plan B drug costs.

With Medicare Part B, federal officials act on behalf of beneficiaries in making decisions about which drugs and treatments get covered under the program and which don't, all without direct communication with or input from the population that is directly impacted.

We proposed that the 66 million Medicare beneficiaries should be allowed to vote each year to set a target for Part B premium increases. Many seniors struggle with premium increases, so it makes sense they should have a say. Once a budget is set, Centers Medicare & Medicaid Services will have a clear mandate in making difficult coverage decisions for expensive new treatments.

One of the factors behind the turmoil in the House of Representative is the growth of the federal debt. Underlying the projected growth debt is an increase in spending for entitlement programs such as Medicare. Medicare will have a deficit of $440 billion this year, growing to $823 billion in 2030. Our proposal would essentially have seniors set a budget

for Medicare. This step would dramatically change the discussions in Washington about Medicare growth and put real pressure on drug prices.

More information: Barak D. Richman et al, Engaging Medicare Beneficiaries in Coverage Choices, *JAMA* (2023). DOI: 10.1001/jama.2023.6371

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