HIGH DRUG PRICES PUT PRESSURE ON HEALTH CARE BUDGETS

Drug Pricing Around the World

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On August 30, the FDA approved the world's first gene therapy, Novartis's Kymriah™. This is a CAR-T cell therapy that has proven effective to treat pediatric acute lymphoblastic leukemia (ALL) that does not respond to conventional chemotherapies. This novel therapy that has saved lives by putting young cancer patients into remission comes with a hefty price tag. Novartis said it will charge $475,000 USD for the one-time treatment and, while the company has agreed to link payment to successful outcomes, [21] it reminds us of the pressure on health care budgets.

Health care budgets worldwide are strained as drug costs continue to rise, coupled with the introduction of blockbusters and orphan drugs that can cost hundreds of thousands of dollars per patient annually. Providing medicines and treatments that are effective at a price patients and governments can afford has governments seeking ways to control prices.

United States

In the United States, the fragmented nature of health care delivery means that there is almost no price regulation. Both state-sponsored Medicaid (for the poor) and Medicare (for the elderly) are forbidden by law to negotiate price with pharmaceutical companies, though governments and insurers do negotiate rebates and discounts, and Medicaid gets a mandated discount. In fact, these rules lead to higher prices for drugs by rewarding physicians who choose costlier alternatives. [4] President Trump had said he wanted to let Medicare – by far the pharmaceutical industry's biggest customer – negotiate drug prices, though 56 percent of biotech executives believe this would be a bad move. [5] Trump has since backed off that position.

Erin Fox

"In the US there are no limits to what drug makers can charge," said **Erin Fox**, the director of the Drug Information Service at the University of Utah Health Center and an expert on drug pricing in the United States.

Higher prices in that country are caused by a number of factors: there are the monopoly rights that come with FDA approval and patent protection; [6] Medicaid must fund all FDA-approved drugs even when a cheaper alternative is available; [19] there are legal tactics that prevent competition from, for example, generics that would drive down price; [6] and there continues to be considerable delays in the approval process for generic drugs.

New Zealand

At the other end of the spectrum is New Zealand, one of the many countries that manage drug costs using a national formulary system and negotiating prices with pharmaceutical manufacturers. PHARMAC is a national agency, created in 1993, that manages government funding of drugs. It does not purchase drugs; instead, it decides which medicines will be funded by the government and negotiates rebates with drug makers. These rebates can be as high as 99 percent and mean that New Zealanders usually pay $5 for a prescription regardless of the cost. [7] The government doesn't – that is, it can't afford to – cover all medicines. "The number of medicines funded isn't the important thing," a spokesperson for PHARMAC said. "It's the health gain we get that's important."

United Kingdom

The National Health Service (NHS) of the United Kingdom chooses which drugs are stocked in its formulary based on a risk-benefit analysis that measures what it calls quality-adjusted life years added, or qualy. [8] The NHS usually won't approve a drug with a price exceeding about $37,000 per qualy. This limit has meant that some of the modern – and expensive – cancer drugs have not been recommended by the NHS. For example, it rejected Kadcyla, used in the treatment of metastatic HER2-positive breast cancer, because of its price tag of about $110,000. [1] In 2010 the government created a special fund for cancer drugs that, because of cost overruns, had to be reviewed last year. [8]

European Union

All of the European Union countries, except Germany, Sweden, and the UK, rely on external reference pricing (ERP) for some or all of their medicines. ERP is a practice of averaging the price of drugs in a number of foreign jurisdictions then using this benchmark to set the domestic price or to negotiate one with drug makers. This system means that Europeans routinely pay less than half what Americans pay for prescription drugs. [2]

The European Commission released a study in late 2015 on drug pricing for member states to address the impacts of ERP on patient access to medicines and lowering prices. [9] It found that there is a disincentive for drug makers to launch new drugs in countries with lower prices and that firms tend to introduce new drugs in countries with high prices to boost the average when other countries benchmark.

The report recommends creation of a European database of prices, including discounts that have been negotiated and are currently kept confidential. It recognizes the threat that the pharmaceutical industry would oppose such disclosure and companies have stated they would stop providing discounts to poorer countries if discounts were made public. [10]

Canada

Canada uses a version of ERP to determine what it will pay for drugs, which is roughly the average paid

in seven other countries. The federal government steps in only if the price fluctuates far from that average. Unlike countries in Europe, Canada uses the United States as one of its references, pushing up prices so that Canadians pay more for drugs than anyone in the world outside of their neighbors to the south. [7] For example, Amoxicillin, made by the Canadian-owned Apotex, is six times more expensive than it is in New Zealand [7].

Canada is also the only country with universal healthcare that does not also have universal pharmacare. Instead, consumers pay for medicine in one of three ways: the self-employed pay out of pocket; prescriptions for the elderly, the poor, and for Indigenous people are partially funded by the government; and the employed have private health plans the premiums of which are mostly covered by employers.

Governments and manufacturers in emerging markets in Asia and Northern Africa sometimes provide tiered pricing for products. As Maurice Parlane, director at New Wayz Consulting in Auckland and director of ISPE Australia has noted, they need to balance affordability and accessibility by offering medicines with different prices for the domestic market and for export. [11]

The need to balance R&D with price in the US

Countries that negotiate drug prices typically have lower prices. The United States is not one of those countries – yet. Soon after taking office President Trump suggested that, "We're the largest buyer of drugs in the world, and yet we don't bid properly. We're going to start bidding. We're going to save billions of dollars over a period of time." [12] Whether this will come to pass is unknown.

The industry rebuttal to criticism of higher prices in the United States is that they encourage R&D and allow firms to recoup costs of both successful and failed drug candidates. While actual costs are difficult to pin down, studies put the price to discover, test, produce, and market a new drug at between hundreds of millions of dollars to as much as $2.6 billion. [13, 14]

Many believe the United States market subsidizes the R&D costs in other countries and, if prices were to decrease there, R&D budgets would probably shrink as well. [1] Not everyone agrees with this argument, citing figures that companies spend less than one-fifth of their revenue on R&D. [6] The average spend on R&D for the ten largest pharmaceutical companies is well over $6 billion [15] and is much less than what is spent on marketing. [16]

"Pharma will say high prices are needed or we won't have innovation, but the EU and Japan have the same drugs we do, just at a lower price," said Fox. "It's not that the US is getting the drugs earlier. While there is some truth that the US funds R&D for the entire world, if these innovative products are priced so high that patients and health care systems can't afford them, it doesn't matter."

"While there is some legitimacy in the pharma argument that they have R&D wrapped up in a drug like Sovaldi, we still believe it's overpriced for its benefit to society," said **Scott Knoer**, chief pharmacy officer at the Cleveland Clinic, an academic hospital renowned worldwide for its treatment of cardiovascular disease. He cites the glaring examples of price increases for generics – for example, nitroprusside and isoproterenol, which have been

around for decades and saw a large price increase in early 2015 – that come from companies that haven't done much R&D at all. "Valeant bought these two drugs, didn't do any R&D, and jacked the price up. If our clinic had continued to use the same amount of those drugs after the price increase we would have been spending over $8 million more."

Scott Knoer

Instead, for drugs that suddenly become much more expensive, the Cleveland Clinic switches to smaller bags to reduce waste and, in some cases, uses a different drug. "We're constantly evaluating the cost-benefit of pharmaceuticals," Knoer said. "Sometimes we're stuck and there's not another drug."

Then there are the blockbusters, such as Biogen's Spinraza for spinal muscular atrophy in infants. It has a price tag of $750,000 for the first year of treatment and $375,000 for each subsequent year.

Jeffrey Rosner is the senior director of pharmacy purchasing at the Cleveland Clinic. He said that insurers are rationing care for expensive medicines and this impacts patient care. The really expensive drugs, such as Sovaldi and Spinraza are good examples. "Sovaldi is being given only to those who have significant liver disease," he said. "They're waiting for others to get sicker before they give them the drug." With the potential repeal of Obamacare, many patients may have caps placed on their insurance coverage. In this case, a prescription for Spinraza could mean that a family would reach its lifetime coverage limit by the time their infant is two or three years old.

Prices are only going up

"It's like we're playing whack-a-mole," said Knoer. "It's not one drug, it's all these things together that are eating at our budget. The average brand name drug has increased in price over ten percent per year, which means they double every seven years. Since the great recession of 2008 prices have doubled, but salaries certainly haven't."

Total spending on medicines in the United States was 8.5 percent higher in 2015 according to a report from IMS Institute for Healthcare Informatics. [17] Specialty drugs for hepatitis and oncology rose 21.5 percent and a majority of biotech executives believe we're entering a new era in drug pricing. [5]

Fox, who recently published a paper that associates high prices with drug shortages, [18] discussed other ways that high prices affect consumers. "Sometimes patients make the choice between paying rent or buying medicine," she said. "Even patients who can afford it may choose not to pay for expensive meds. When patients are not compliant, chronic diseases

COMPARISON SHOPPING

The ever-increasing price of prescription drugs is straining healthcare budgets worldwide, in both poorer and developed economies. Poster child for this has been the price of Sovaldi and Harvoni, which have proved successful in the treatment of hepatitis C, but come at a wholesale price of $84,000 per treatment. [1]

"There are so many patients that would benefit from these drugs that, if state Medicaid gave it to every patient that it could help, it would bust every state Medicaid program," said Scott Knoer, chief pharmacy officer at the Cleveland Clinic.

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> ~ Scott Knoer

The International Federation of Health Plans (IFHP) 2015 survey of drug prices highlighted the wide range of prices for prescription drugs from country to country. [2]

In every example cited, the cost in the United States was substantially higher than in any other country. For example, Xarelto, used to treat blood clots, was well over twice as expensive in the United States as in the United Kingdom and six times the price of the drug in South Africa. Similar spreads existed for Humira (rheumatoid arthritis), Avastin (cancer), and Tecfidera (relapsing multiple sclerosis).

This doesn't take into account the shocking price increases for generics – from Turing Pharmaceuticals, Valeant, and, most recently, Marathon Pharmaceuticals – that have shone an unfavourable light on the pharmaceutical industry.

In January, when Marathon announced it was setting a list price of $89,000 for deflazacort, which recently received Food and Drug Administration (FDA) approval for sale in the United States, the negative response was swift. Senators Bernie Sanders and Elijah Cummings noted that the drug had been available from overseas manufacturers for a small fraction of that cost and denounced the price increase. The company delayed release of the drug. [3] Also in January, three drug makers were accused of conspiring to raise insulin prices. [20]

can get worse, meaning more trips to the hospital or ER and more expensive care." The most glaring example is that patients won't fill their prescriptions or, if they do, stretch them by taking a lower dose or skipping a dose.

Another problem is that, in many cases, consumers are shielded from high prices. "In the US, drug companies use discount coupons and other incentives – basically marketing schemes – for those who have insurance and aren't on a government-funded program," Fox said. "The patient gets the meds for free or pays a low co-payment and the additional cost is passed on to the insurance company, which raises premiums for everyone. It sounds like a good deal, but it's not accessible to everyone."

She said that the coupons are driving up health care costs. "There may be an older generic product that works just as well, but a physician will give a patient a coupon for the latest iteration of this drug that costs a lot more." Insurers can choose not to pay for the more expensive drug, but the pharmaceutical company might offer them a rebate if they use the

new drug. "Meanwhile, premiums keep going up," Fox said.

High prices also affect hospital budgets, which have fixed operating expenditures for procedures listed under diagnostic related groups. If the price of a medication used in a procedure increases, it eats into the rest of the budget allocated. Knoer used the example of a hypothetical $100,000 procedure. "We get the same amount whether we spend $6 on medicine for that procedure or $90,000," he said. "If the price of drugs go up, we make less and can potentially lose money."

Rosner said the Cleveland Clinic had a decrease in operating income last year that was attributable, in part, to a 19 percent increase in drug prices. "These increases are due to the egregious price increases we've all heard about as well as for the new drugs that are extremely expensive."

Would allowing the US government to negotiate price or set up a national formulary be a solution?

"The reason negotiating price does work in many other countries is that the government is the sole source purchaser," said Rosner. "In the US it's much more fragmented, with employers, insurance companies, PBMs [pharmaceutical benefit mangers], and private pay."

"Negotiating prices would decrease costs for government payers, but it could wreak havoc with the rest of the market," said Knoer. "If the government dictated price for Medicare and Medicaid, as it currently does for the Veteran's Administration, it's likely that drug companies will jack up the price for anyone with private insurance or self-pay."

Fox thinks negotiating might help in the United States despite the fragmentation of the payment and reimbursement system. "PBMs do try to negotiate, but often they're negotiating rebates and there isn't a lot of transparency about how the money is flowing. Just because a company is charging $100 thousand for a medicine doesn't mean that the drug company is getting all of it. Letting the government, which is the largest payer, have some form of negotiation is a good start. Every other country does it, why shouldn't we? It clearly doesn't cause detriment to other countries because they have access to these same innovative treatments that we do."

The Cleveland Clinics' Knoer suggests more transparency. "I'd like to see the free market work because it's clearly not working now," he said. "The new drugs have to be priced more reasonably."

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