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Authors
Jenei, Kristina
Prasad, Vinay
Lythgoe, Mark P

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1 School of Population and Public Health, University of British Columbia, Vancouver, British Columbia, Canada

2 Department of Epidemiology and Biostatistics, University of California San Francisco, San Francisco, United States

3 Department of Surgery and Cancer, Imperial College London, London, United Kingdom

Corresponding author: K Jenei
kjenei@mail.ubc.ca

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High US drug prices have global implications

Lower income countries need better protection from an unfettered US market

Kristina Jenei, [1] Vinay Prasad, [2] Mark P. Lythgoe[3]

This is a critical time for pharmaceutical reform in the United States. The Biden administration introduced the Build Back Better Bill, which included several provisions to reduce prescription drug costs.[1] But the fate of the bill is uncertain. Although these reforms have direct implications for the US healthcare system, their international impact is seldom appreciated. Given the global influence of the US drug market and increasing unaffordability of medicines worldwide, the stakes of pricing reform are high.

The US has the largest drug market in the world, estimated at over $480bn, over four times larger than the next country (China $88.3bn), and accounts for an estimated 46% of global pharmaceutical sales.[2] The US is also the world's largest funder of biomedical research, so it is responsible for funding a substantial proportion of global medicine development. For this reason, many drug and biotechnology companies have a large presence in the country. But drug prices are so high in the US that companies typically earn enough to cover all global research and development costs associated with a new molecule.[3] These features combined—research and development and potential revenues—are a powerful incentive for manufacturers to prioritise admission into the US market.

There are several ways in which high US drug prices affect other countries. First, drug prices are often set by whatever the US market will bear. The US is the only major economy without any central direct drug price negotiation, so individual public and private insurers negotiate directly with manufacturers. In a decentralised and fragmented environment, institutions cannot exert major influence on costs. Americans spend, on average, twice as much on medicines as other industrialised countries.[4] Drug companies set high prices and increase those prices, without major restraint, each year, which means medicines are often first launched in the US.[5] Other countries must then negotiate for drugs that have been priced for an unfettered US market. Even after negotiated discounts, medicines in Canada, France, and Germany are only 10-15% cheaper than in the US.[4]

Second, many countries set their medicine prices based on "list prices" in economically similar countries— a practice called international reference pricing. In Canada, the Patented Medicine Prices Review Board conducts a "median international price comparison," in which the median list prices from seven countries, which typically includes the US, are averaged to form a price ceiling.[6] The relation between international reference pricing and Canadian drug prices warrants further exploration, but given that US drug prices are the highest in the world, cross border comparisons inevitably increase the price of new drugs in Canada. Further, drug companies are aware of national strategies to limit costs, such as international reference pricing, and prefer to launch drugs in countries willing to pay higher costs, thus limiting the effectiveness of price negotiation strategies.[5]

Third, several low and middle income countries rely on regulatory decisions from foreign agencies to approve new medicines. India,[7] countries in Latin America, the Caribbean,[8] and Africa[9] have all reformed their drug approval processes to align with decisions from the US Food and Drug Administration. One study, for example, showed that 80% of all medicines approved in Argentina relied on safety and efficacy evaluations made by the FDA.[10] But the FDA does not consider drug costs in regulatory decision making. Further, less than a third of drugs approved in the US over the past decade were deemed to have high therapeutic value.[11] Low and middle income countries that align regulatory decisions with the FDA are not prioritising the most effective or cost effective medicines. Drug prices in Argentina have risen in line with increases in the US—the average cost of prescription medicines is now $7974 per month (oncology medicines $17 700).[10] A similar trend was observed in Brazil[12] and other middle income countries, such as Ecuador[13] and Colombia.[14] When adjusted for gross domestic product per capita, these costs are even less affordable relative to the US.[15] Investing resources on marginally effective medicines constrains health systems, harms individuals, and jeopardises universal health coverage.

Inability to exert any downward pressure on drug costs in the US keeps prices high globally. Proposals in the Build Back Better Bill are limited, so US policy makers should pass legislation now as a first step towards controlling high drug costs.[1] Further, instead of relying solely on decisions made by big global regulators such as the FDA, countries should be encouraged to join consortiums of medicines regulators to pool resources and build regulatory capacity, such as the Access consortium, which includes the UK, Canadian, and Australian regulatory authorities.[16]

Greater collaboration among regulators would increase efficiency, transparency, and consistency of approval decisions across countries. Other opportunities exist through the Fair Pricing Forum and the Oslo Medicine Initiative,[17] both led by the World Health Organization. These initiatives develop tools,[18] increase transparency, and nurture solidarity between countries trying to tackle high medicine costs and meet the UN Sustainable Development

Goals. Lastly, the added value of new medicines must be considered in US regulatory decisions. Approving medicines without any consideration of their therapeutic value has profound consequences—not just for the US but for health systems worldwide, and disproportionately for low and middle income countries.

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