Weekly Checkup

The Case for Protecting American Innovation

JOHN WALKER, PARTH DAHIMA | AUGUST 2, 2024

The Biden Administration has sighted any number of targets it blames for high drug prices, from pharmacy benefit managers to greedy drugmakers. **It seems, in the Biden imagination, there's always some cackling villain pulling the strings in the health care market, if not to make a quick buck then for the simple thrill of causing pain.** The narratives always have a nice Avengers-movie ring to them, but over on the *policy* side of health care, there are specific, traceable problems that cause drug prices to rise and reduce innovation. In at least one case, instead of searching for the monster under the bed, the Biden Administration should venture a look in the mirror. Today, **let's look at a pressing issue that is directly undermining U.S. drug innovation and could dangerously reduce the country's access to critical and innovative generic drugs: the Biden Administration's attack on U.S. intellectual property (IP) rights.**

Here are the basics. Pharmaceutical IP rights are a legal framework designed to protect and encourage new drug innovation by rewarding manufacturers with market exclusivity power when they undergo costly research and development to bring a new drug to market. The Drug Price Competition and Patent Term Restoration Act, more commonly known as the Hatch-Waxman Act, enables manufacturers to sell their drugs with market exclusivity to recoup their costs. After a few years, the patent expires, allowing other drug manufacturers to begin reproducing the drug as a more affordable generic. By enabling manufacturers to charge a higher upfront cost in exchange for an expedient generic process several years later, Congress effectively pulled the sword from the stone, incentivizing manufacturers to innovate while still allowing for cheaper drugs to gradually reach the market. **Considering the cost to bring a new drug to market ranges from $314 million to $4.46 billion , it's no surprise that IP rights and market exclusivity are the primary drivers of the country's global dominance in prescription drug innovation.**

As American Action Forum experts have discussed at length, this steady stream of accessible and inexpensive generics is at risk. **Spurred by ineffective price controls of the Inflation Reduction Act, threats by the Biden Administration to seize patents with the use of march-in rights, and the administration's waiving of Trade-Related Aspects of Intellectual Property Rights protections for COVID-19 vaccines in 2022, pharmaceutical manufacturers are reducing their production of innovative drugs in favor of more cost-effective generic lineups.** As highlighted by the House Budget Committee, "[The IRA] will cause patients to lose access to an estimated 40 percent of new medicines or up to 139 new therapies over the next decade." With some of the biggest global drugmakers eyeing new deals in China and Singapore's Biopolis, Congress would be wise to strengthen IP rights rather than punish U.S. innovation.

The other problem with the Biden Administration's tale of heroes and villains dictating large-scale supply and demand trends in the pharmaceutical industry is that it's not all that accurate. And while some lawmakers continue to raise concerns about disproportionately high drug costs preventing many in need from accessing critical medications, the data shows a much different picture. As explained by the Association for Accessible Medicines, "the average generic copay is $6.61 compared to an average out-of-pocket cost of $55.82 for brand-name drugs."? Not only does the average generic medication cost less than $7, the Food and Drug Administration estimates that 91 percent of all prescriptions filled in the United States are generic drugs. Effectively, most insured individuals in the United States have respectable access to a growing stream of innovative and inexpensive generics.

While the Biden Administration's folktale is certainly amusing and makes for good politics, the policies undergirding this detachment from reality are destructive. Over in the real world, Congress has a significant role to play in bringing down drug costs and at the same time preserving the country's dynamic drug innovation. It could start by strengthening domestic IP rights, working to incentivize drugmakers to remain in the United States. After all, it is difficult to confiscate your way to lower prices.

PRESCRIPTION DRUGS UNDER FUTURE PRICE NEGOTIATION

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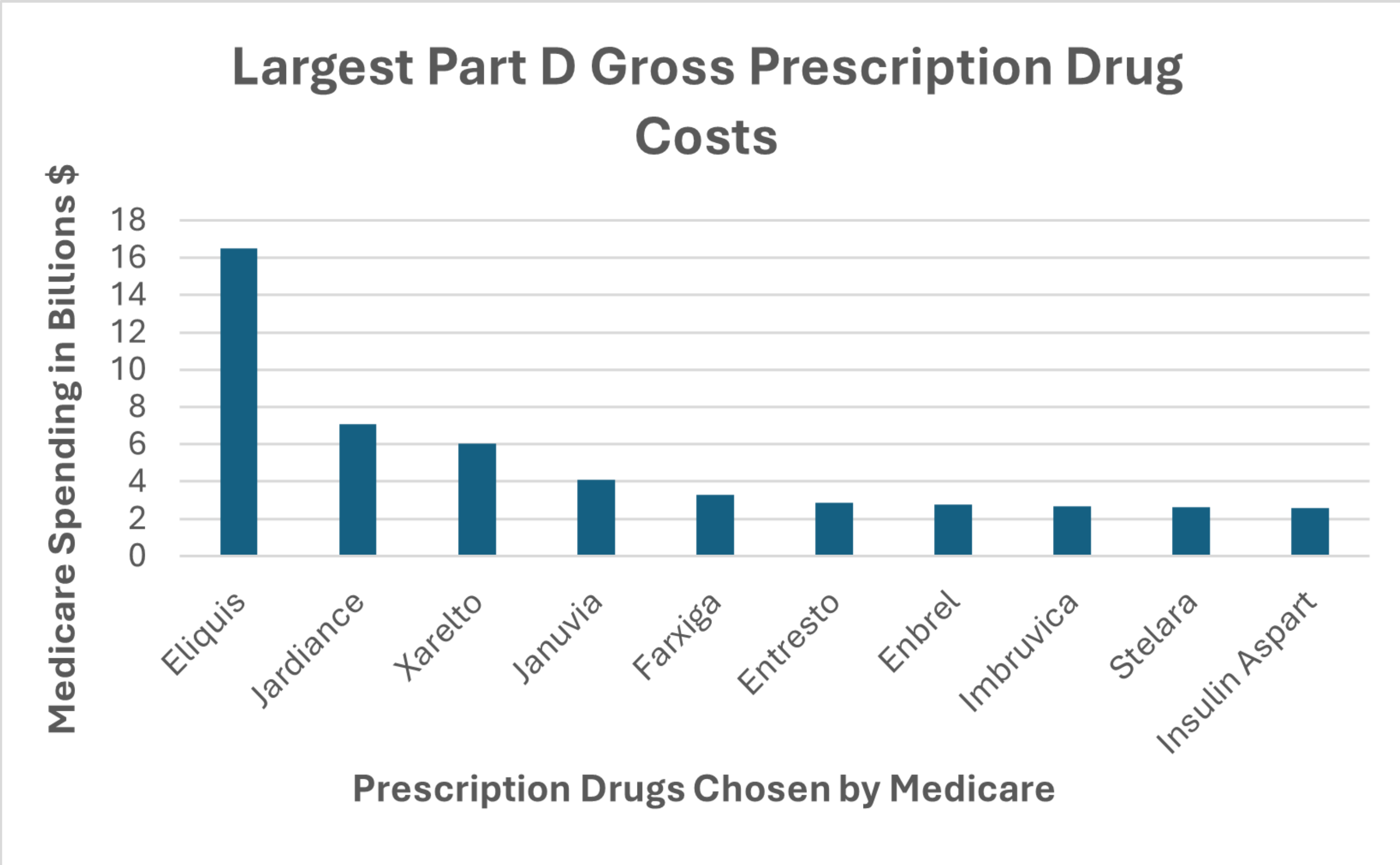
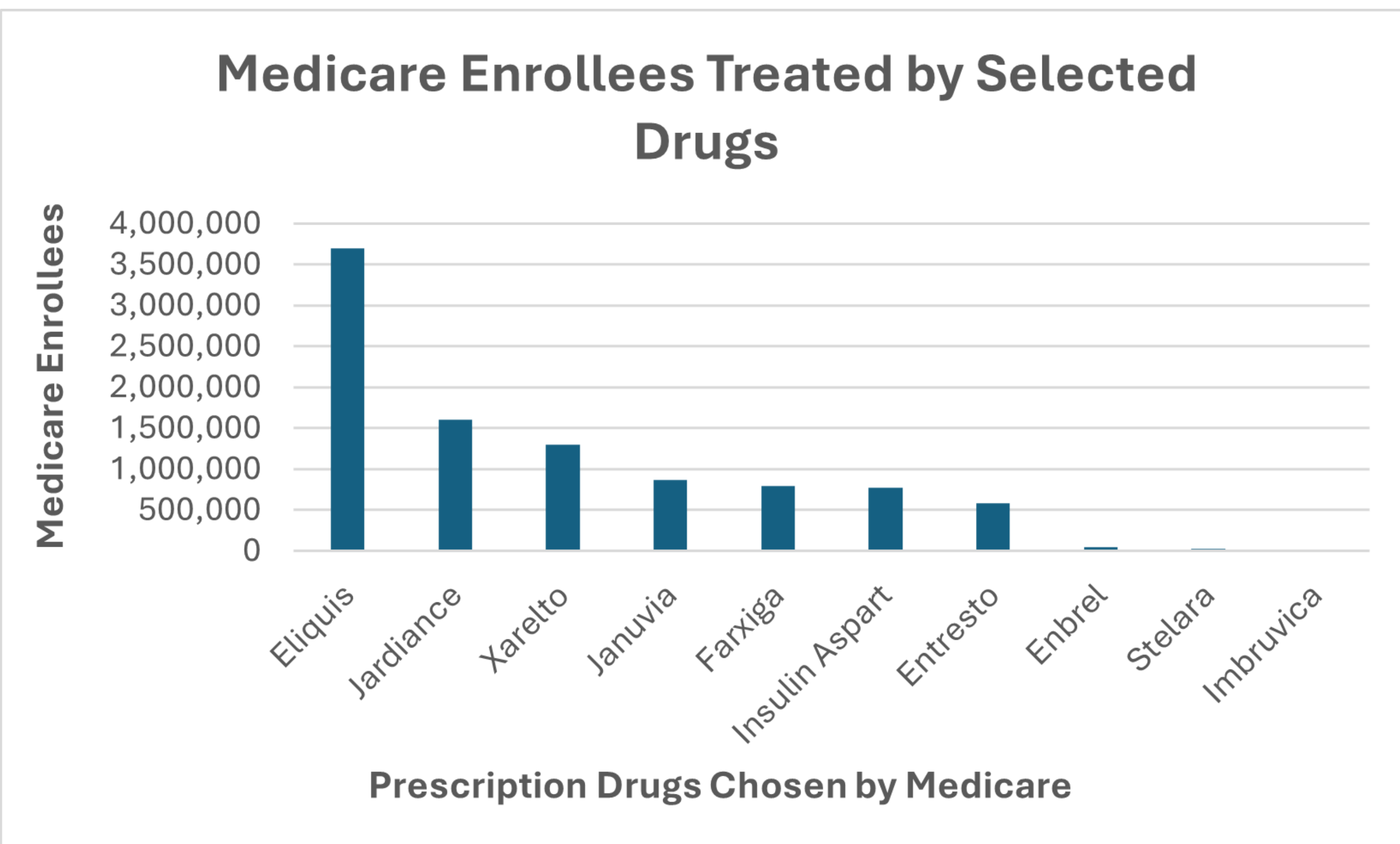
The passage of the Inflation Reduction Act in August 2022 provides Medicare the purview to directly negotiate a range of single-source brand-name Part B and Part D drugs. According to the official timeline, the prices chosen through negotiation will be effective by January 1, 2026. The 10 prescription drugs listed for negotiation were chosen by highest total expenditure under Part D.

The graphic below represents the 10 drugs chosen by Medicare and each drug's Part D gross cost from June 2022 to May 2023. The drug with the largest cost is Bristol Myers Squibb's Eliquis, with an estimated total of $16.5 billion. Jardiance, produced by Boehringer Ingelheim, follows in second with a $7.1 billion share of Part D prescription drug costs. In third is Johnson and Johnson's Xarelto, accounting for $6 billion in costs. The remainder of the drugs individually account for $4.1 billion or less in costs. The sum cost of the 10 drugs selected totals to $50.5 billion, with Eliquis notably consuming 32.7 percent of the total cost.

The second graphic represents total Medicare enrollees treated by the drugs selected for negotiation from June 2022 through May 2023. Leading the list is Eliquis with 3.7 million individuals treated under Medicare. In second and third are Jardiance and Xarelto, with 1.6 million and 1.3 million Medicare enrollees respectively. Of note is insulin aspart – produced by Novo Nordisk – which, despite having the lowest Medicare spending cost at $2.2 billion, ranks sixth highest in Medicare enrollees treated at 777,000.


Largest Part D Gross Prescription Drug Costs
Medicare Spending in Billions $
18
16
14
12
10
8
6
4
2
0
Eliquis
Jardiance
Xarelto
Januvia
Farxiga
Entresto
Enbrel
Imbruvica
Stelara
Insulin Aspart
Prescription Drugs Chosen by Medicare


Medicare Enrollees Treated by Selected Drugs
Medicare Enrollees
4,000,000
3,500,000
3,000,000
2,500,000
2,000,000
1,500,000
1,000,000
500,000
0
Eliquis
Jardiance
Xarelto
Januvia
Farxiga
Insulin Aspart
Entresto
Enbrel
Stelara
Imbruvica
Prescription Drugs Chosen by Medicare

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