ELIQUIS AND XARELTO: LOCKSTEP PRICE HIKES AND PATENT GAMING EXPLOIT PATIENTS AND TAXPAYERS

This report examines the practices of BMS/Pfizer and Johnson & Johnson's lockstep price hikes and patent gaming on two blockbuster blood thinners and the implications for patients and taxpayers.

Blood thinners — also called anticoagulants — are critical medications that help treat and prevent blood clots. More than 8 million Americans take a blood thinner regularly, including people who are at risk of stroke or heart attack and those with an irregular heartbeat called atrial fibrillation. Until 2010, the standard of care for blood thinners was a medication called warfarin — which, while inexpensive, carries a high risk of bleeding and requires frequent lab tests to monitor that bleeding risk.

In 2011, a new category of anticoagulants entered the market. These novel products were revolutionary for patients because they were less risky and did not require routine lab tests. The first products, Eliquis and Xarelto, were priced at over \$200 for a month's supply — major sticker shock at a time when a month's supply of warfarin cost less than \$10.1

The sticker shock did not stop there. The prices of both drugs have risen every year, far outpacing the rate of inflation. As of January 2022, the prices of a month's supply of Eliquis and Xarelto are \$529 and \$516, respectively. While the medications have improved the quality of life for millions of patients, the pricing behavior of the companies that manufacture these two blood thinners has led to grave consequences for patients, insurers, and taxpayers.

Addressing the high price of these medications is imperative to patient access and carries significant implications for health equity amid and beyond the ongoing COVID-19 pandemic. Black Americans, who are at higher risk for many diseases requiring blood thinners due to historic and structural inequities, may have unequal access to anticoagulants, in part due to cost. Anticoagulants have also become increasingly critical for preventing blood clots in patients with COVID-19.

ELIQUIS AND XARELTO AT A GLANCE

Eliquis | Manufactured by BMS/Pfizer²

- Entered the market in 2013 at a price of \$250 for a monthly supply
- Currently priced at \$529 for a monthly supply
- Price increase since market entry: 111%
- Fourth <u>best-selling</u> drug in the world in 2020
- Price is <u>5x</u> higher in the United States than in other countries
- 2.6 million Medicare Part D beneficiaries took Eliquis in 2020
- #1 most costly drug for all of Medicare in 2020

Xarelto | Manufactured by Johnson & Johnson²

- Entered the market in 2011 at a price of \$218 for a monthly supply
- Currently priced at \$516 for a monthly supply
- Price increase since market entry: 136%
- Tenth <u>best-selling</u> drug in the world in 2020
- Price is up to <u>10x</u> higher in the United States than in other countries
- 1.1 million Medicare Part D beneficiaries took Xarelto in 2020
- #3 most costly drug for all of Medicare in 2020

¹ All pricing data is from AnalySource® as reprinted with permission by First DataBank, Inc. All rights reserved. © (2022). Please refer to http://www.fdbhealth.com/policies/drug-pricing-policy/ for more information. Prices are wholesale acquisition cost ("WAC"), or the manufacturer's published list price to wholesalers.

² Eliquis is co-marketed by Bristol Myers Squibb and Pfizer, Xarelto is sold by Janssen, a wholly owned subsidiary of Johnson. & Johnson.

HISTORY OF PRICE HIKES IN LOCKSTEP

Competition among products is supposed to lead to lower prices in the pharmaceutical market. But, a decade after the novel blood thinners entered the market³, their prices remain out of reach for many patients due to a long history of unjustified price hikes. Driven in part by spending on marketing and advertising, the two medications have achieved skyrocketing prescriptions and profits. Because of their superior clinical benefits, millions of patients have switched from warfarin to Eliquis and Xarelto. Together, the pair has captured the majority of the novel blood thinner market. By 2020, the number of Medicare Part D beneficiaries taking either Eliquis or Xarelto had reached 3.8 million.

Since there are no generic competitors on the market for Eliquis and Xarelto, the manufacturers are able to dictate prices to patients and taxpayers. Instead of competing for customers by undercutting each other's prices in an effort to gain market share, the companies have instead increased their prices in lockstep over the past decade. This tacit agreement allows both companies to extract increasing amounts of profit without any meaningful changes to the drugs. This type of lockstep pricing behavior is driven by corporate greed and occurs at the expense of patients and taxpayers.

WHAT IS SHADOW PRICING?

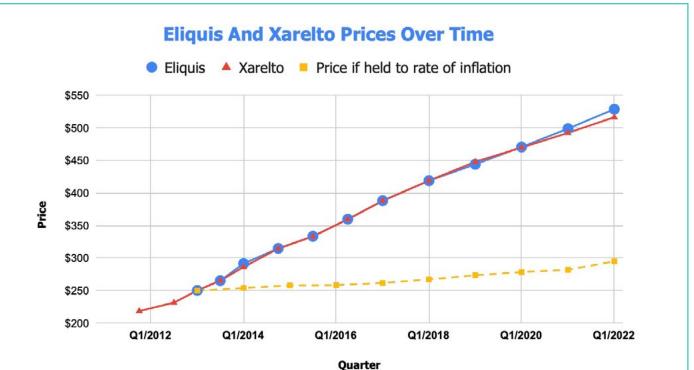
Shadow pricing occurs when a company consistently follows the price increases of a competitor in order to maintain high and rising prices. The failure of drug companies to compete on price demonstrates the mutual benefit gained by companies that choose to reject competition in favor of sharing a market with high and ever-rising profits.

THE COVID-19 CONNECTION

In 2021, the National Institutes of Health found that treating certain COVID-19 patients with blood thinners improved outcomes. Both Eliquis and Xarelto have since been recommended as part of treatment guidelines for COVID-19.

Early in the COVID-19 pandemic, reports that Eliquis could prevent strokes in patients seriously ill with the virus prompted a spike in demand for the drug. Despite the public health implications and rising demand, Johnson & Johnson and BMS/Pfizer have both hiked the prices of Eliquis and Xarelto twice during the pandemic. Blood thinners may become even more critical in the future due to emerging evidence that long COVID patients are at an increased risk of blood clots.

³ An additional brand-name novel anticoagulant named Pradaxa also entered the market around the same time as Eliquis and Xarelto. Pradaxa (and any other novel anticoagulants that have since entered the market) is not a focus of this report because it has not achieved the same market traction and does not participate in lockstep price hikes.



A CLOSER LOOK AT THREE SHADOWY HIKES



Summer 2015:

- On Aug. 1, 2015, both Eliquis and Xarelto were priced at \$314 for a month's supply.
- On Aug. 5, 2015, Johnson & Johnson increased Xarelto's price to \$333.
- Just three weeks later, BMS/Pfizer matched that hike by raising Eliquis' price to \$333 as well.

Spring 2016:

- Eliquis' price was hiked from \$333 to \$359.
- Just five days later, Johnson & Johnson mirrored the hike, raising the price of Xarelto to \$359.

Winter 2017:

For the third year in a row, both drugs increased prices in lockstep, from \$359 to \$388.

IMPLICATIONS FOR PATIENTS AND TAXPAYERS

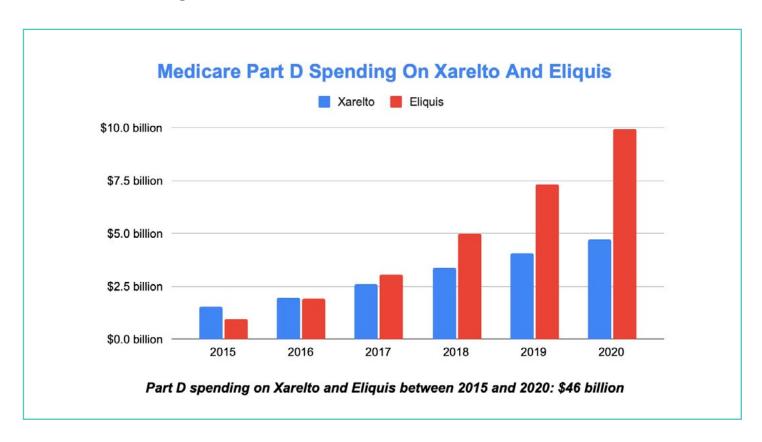
Patients suffer grave health and financial consequences due to the high prices of Eliquis and Xarelto. Many patients who are prescribed blood thinners are Medicare beneficiaries, who have a median income of \$29,650. A recent report from the Department of Health and Human Services found that 3.5 million adults age 65 or older had difficulty affording medications, with the highest rates reported from

Black and Latino adults. Many patients who struggle to pay for their blood thinner may be forced to switch to warfarin because it is more affordable than Eliquis and Xarelto. This switch puts them at higher risk of dangerous bleeding and necessitates burdensome, frequent lab tests.

Taxpayer-funded programs such as Medicare disproportionately shoulder the burden of the rising prices for medications. Price increases and a rising number of beneficiaries taking the medications have catapulted

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both drugs to the top of the list for the most costly medications for all of Medicare Part D. Since 2015, Medicare Part D has spent more than \$46 billion on the two drugs. In 2020, Eliquis and Xarelto were the most costly and third-most costly drugs for the program. Medicare Part D's spending on Eliquis in 2020 was a record-breaking \$9.9 billion.



CONSEQUENCES FOR PATIENTS

1 need a blood thinner called Xarelto to protect me against blood clots. I've taken the drug for the last 12 years and watched its price go up, up, up. It costs \$516 for a month's supply. Living on a fixed income, my budget is strained by the price of my prescriptions, but I cannot live without them."

 Connie Lindy, Middletown, DE

"After a quadruple bypass surgery that saved my life. I was prescribed seven medications to prevent me from having heart attacks in the future. I'm very thankful for their existence. However, they are a real financial burden. I take the blood thinner Xarelto to prevent dangerous blood clots that can lead to heart attacks. It is priced at over \$500 for a 30-day supply. I used to work in pharmaceutical sales, and I have been in meetings where we discussed pricing. I know firsthand that companies set prices at the highest price the market will accept. It's outrageous and unfair."



 Sheldon Armus, Boynton Beach, FL

'I live with lupus and am prescribed many very expensive medications to treat the symptoms of my condition. I've had to spend my entire paycheck to get my prescription drugs. One of those expensive drugs is Eliquis, which I take to prevent dangerous blood clots. I will be on it for the rest of my life. I often worry about how I'll make ends meet while still affording my drugs. Without them, my life would be at real risk! It's no way to live, but I don't have a choice."



 Ashley Suder, McMechen, WV

'The exorbitantly high price of the Eliquis take has forced me to sell one of my cars, take out extra loans, and cut back wherever I can on everyday necessities. I live with the possibility that I may one day not be able to access all the medications I need simply due to high prices. When that happens, I will face the possibility of life-threatening blood clots."



Gibsonia, PA

PROFITS FUEL MARKETING AND ADVERTISING. **NOT RESEARCH AND DEVELOPMENT**

When lobbying against reforms to lower drug prices, drug companies often say that high prices are necessary to fuel research and development.

In reality, a recent study found that 7 out of 10 drug companies spent more on sales and marketing than research and development during the COVID-19 crisis.

Xarelto's manufacturer, Johnson & Johnson, spent \$22 billion on sales and marketing and \$12 billion on research and development in 2020. In 2019, the company shelled out an eyepopping \$122 million advertising Xarelto on TV. The following year, BMS/Pfizer surpassed Johnson & Johnson by spending \$170.5 million advertising Eliquis on TV.

Advertising spending translates into generous returns for drug companies, often at the expense of taxpayer-funded programs. A recent government report found that the costliest drugs for Medicare were also among the record spenders on direct-to-consumer advertising, and that ads for drugs like Eliquis may have led to increased taxpayer spending on the product.

THE ANTICOMPETITIVE BEHAVIOR BEHIND THE PRICES

Prescription drug prices decrease when generic companies enter the market with lower prices and force brand-name companies to compete for business. Generic versions of Eliquis and Xarelto present a direct threat to brand-name companies' blockbuster profits, which is why BMS/Pfizer and Johnson & Johnson have employed tactics to block competitors from entering the market.

Patent Thickets

Applying for patents on minor features of a drug — often years after it is initially approved — is a common tactic used by brand-name companies that want to force hopeful generic competitors to undergo costly and time-intensive patent litigation in order to come to market.

Xarelto and Eliquis offer prime examples of this behavior. Johnson & Johnson has applied for 49 patents on Xarelto and been granted 30; BMS/Pfizer has applied for 48 patents on Eliquis and has been granted 27.

As a result, after a decade on the market, neither product has competition on the horizon. When a dozen Eliquis generics began the process of seeking FDA approval in 2017, BMS/Pfizer served the companies with a slew of lawsuits to delay their entry.

By 2019, two generics were approved, but they could be delayed until as late as 2026 due to ongoing patent litigation.

SOLUTIONS

The dynamic between Xarelto and Eliquis is not unique. Millions of patients take medications sold by manufacturers who do everything in their power to avoid competition through collusive and unchecked price increases and thwarting would-be generic competitors. This case offers a compelling roadmap for the areas of our drug pricing system that are in dire need of reform.

In the United States, the prices of Eliquis and Xarelto are 3 to 10 times the prices in other countries because those countries negotiate — and we don't. Brand-name drug companies have the ability to dictate prices to payers, including Medicare, which means patients and taxpayers must pay whatever price manufacturers set. Drug pricing reforms in Congress can change this.

Right now, the Senate is considering drug pricing provisions that the House of Representatives passed in November 2021 as part of the Build Back Better Act. These provisions would include the following:

- Empower Medicare to negotiate lower prices for certain high-cost drugs, including Xarelto. For the first time in two decades, Medicare would be authorized to negotiate directly with drug companies on behalf of beneficiaries.
- Prevent price increases from outpacing inflation. Every price hike on Eliquis and Xarelto since 2011 has outpaced the rate of inflation, highlighting why this policy is imperative for reining in rising prices.

Congress is also considering bipartisan legislation that would eliminate the type of patent gaming used by BMS/Pfizer and Johnson & Johnson to block generic competitors to Eliquis and Xarelto. Many of these bills have already passed through the House and Senate Judiciary Committees and could be swiftly taken up and passed into law.