KATIE PORTER
Putting Orange County families first

SKYROCKETING

How Big Pharma Exploits Launch Prices to Cash in on Cancer

Report by the Office of Rep. Katie Porter

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I. Executive Summary

For decades, soaring drug costs have prevented patients from affording the lifesaving drugs they need. When Big Pharma prices drugs out of reach and patients cannot afford their medications, all Americans suffer. Patients experience worse health outcomes. Families are buried under mountains of medical debt that too many cannot afford to pay. And taxpayers are often forced to foot the bill for emergency care that could have been avoided through regular treatment.

With the Inflation Reduction Act (IRA), Congress and the Biden Administration have enacted transformational reforms that will protect millions of patients on Medicare. Older adults will spend no more than $2,000 out-of-pocket on their prescription drugs. Medicare patients taking insulin will pay no more than $35 per month for the insulin they need to survive. Drugmakers will be prevented from raising the prices of their drugs faster than inflation. And Medicare will finally be empowered to negotiate fair prices for drugs on behalf of patients.

After decades of advocacy from patients and policymakers, the IRA represents a transformative change to drug pricing policy that will protect millions of Americans. But to maximize the benefits of the IRA, lawmakers must tackle the next frontier of drug pricing: exorbitant launch prices for new drugs, which price breakthrough cures out of reach, make it even more difficult to negotiate drug prices, and force taxpayers to bear the cost of the corporate greed of drugmakers.

From 2008 to 2021, the median launch price for new drugs increased by over 8,000%, from $2,115 to $180,087. This is not a problem of a few high-priced outliers. In recent years, the average list price for new medications increased by 20% per year—more than 10 times the rate of inflation. In recent months, this troubling trend has accelerated. In August 2022, the median launch price for 13 new drugs introduced this year is $257,000.

This report analyzes the launch prices for an important subset of drugs—self-administered cancer medications—to demonstrate the benefits of the IRA and to plot a path forward for future reforms.

While cancer drugs are not the only class of medications with damaging launch prices, they represent an important example, including because cancer is the second leading cause of death in the U.S. Oncology drugs launch at prices 3.7 times higher than non-oncology drugs, preventing many patients from receiving cancer treatments. Furthermore, many cancer patients receive coverage through the taxpayer-funded

Medicare program, meaning the high launch prices of cancer medications fall on taxpayers and jeopardize Medicare's resources. Cancer drugs rank among the costliest drugs to Medicare, despite the fact that they are dispensed to a relatively small number of patients.

Using data from the Centers for Medicare and Medicaid (CMS) and analyses from drug pricing experts, our office found:

- **Cancer Drug Launch Prices are Soaring:** Between 2017 and 2021, the inflation-adjusted average launch prices for self-administered cancer drugs increased by 25.8%. If these launch price trends continue, the average new self-administered cancer medication will cost over $300,000 per year by 2025. The 2021 median oncology drug launch price of $232,000 is nearly 2.5 times the median household income for an Orange County family. In addition to self-administered drugs alone, our office calculated launch price trends for the drugs and therapeutic biologics regulated by the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), including drugs administered as infusions. For this subset of drugs, the average price of cancer therapies increased from approximately $185,000 in 2017 to over $283,000 in 2021—a 53.0% increase.
- **High Launch Prices Cause Disproportionate Harms for Seniors, the Uninsured, and the Underinsured:** Uninsured and underinsured patients, as well as patients who receive medication through coinsurance payments tied to a drug's list price, are less likely to fill high-cost prescriptions due to unaffordable out-of-pocket costs. Currently, this population includes Medicare patients. A senior filling a prescription for Imbruvica, a cancer medication that launched at $130,000 annually in 2013, would pay over $12,000 for an annual course of treatment in 2022 under the Part D standard benefit. The out-of-pocket cap in the IRA will save that same senior more than $10,000 per year, amounting to approximately $27,000 in savings over the course of a typical treatment of Imbruvica.
- **Addressing Soaring Launch Prices will Maximize the IRA's Drug Pricing Provisions:** By 2026, when Medicare will first be able to negotiate prices for drugs, the average cancer drug launch price will be nearly $325,000 per year for self-administered cancer drugs and over $525,000 for the class of drugs and therapeutic biologics examined in this report, if current trends identified by our office persist. Proposals targeting launch prices will reduce pressure on the limited negotiation abilities of Medicare and make policy tools like inflation rebates even more effective. Better policies can bring down the launch prices of all drugs, including cancer medications. This report identifies drug pricing

> review boards and pricing policies for drugs launched under the accelerated approval pathway as two helpful reforms. Such changes will help patients receive lifesaving treatment and stabilize costs in our healthcare system.

Like many medications, cancer drugs can be miracles. But when priced out of reach for patients, a medical innovation is not useful. A prescription cannot save a life if it goes unfilled.

The IRA is an important, game-changing first step toward reining in drug costs. The IRA will lower costs for seniors with its out-of-pocket spending cap and will empower Medicare to negotiate for the most expensive drugs. In order to deliver on the IRA's promise to lower drug prices, policymakers must focus on the next challenge: soaring launch prices of new drugs. Bringing down the prices of newly introduced drugs will make the IRA's policies even more effective.

II. Introduction

In 2013, the pharmaceutical giants Pharmacyclics and Johnson & Johnson introduced their new cancer drug, Imbruvica, at a price of $130,000 per year.[1] For those who could afford Imbruvica, the drug worked wonders. More than three-quarters of patients who remained on the drug for 30 months showed no progression in their cancer.[2] Medical experts hailed Imbruvica as a drug that "may make chemo a thing of the past."[3] Yet rather than set a price that patients with cancer could afford, Imbruvica's manufacturers used a six-figure price tag to target a multi-billion-dollar sales figure.[4]

Imbruvica was not the only cancer drug launched at an exorbitantly high price. In the months following Imbruvica's market introduction, public outrage at cancer drug list prices erupted. News outlets published articles citing the "incomprehensible prices" of cancer medications.[5] In 2015, over 100 oncologists joined a statement calling the current pricing system "unsustainable and not affordable for many patients."[6]

Despite the national attention attracted by high cancer drug launch prices, Imbruvica's manufacturers did not lower the drug's price. Instead, they raised it.[7] Between 2013 and 2019, Imbruvica generated $16.3 billion in U.S. net revenues.[8]

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[1] "Imbruvica, Drug to Treat Blood Cancer, Gains F.D.A. Approval," *New York Times* (Nov. 13, 2013) (online at https://www.nytimes.com/2013/11/14/business/drug-to-treat-blood-cancer-gains-fda-approval.html#:~:text=Imbruvica%20will%20cost%20about%20%2491,ever%2Dincreasing%20cancer%20drug%20prices).

[2] MD Anderson Cancer Center, "The Drug That May Make Chemo a Thing of the Past," (2014) (online at https://www.mdanderson.org/publications/conquest/the-drug-that-may-make-chemo-a-thing-of-the-past.h37-1589046.html).

[3] *Id.*

[4] "Imbruvica, Drug to Treat Blood Cancer, Gains F.D.A Approval," *New York Times* (Nov. 13, 2013) (online at https://www.nytimes.com/2013/11/14/business/drug-to-treat-blood-cancer-gains-fda-approval.html).

[5] "Cancer: Unpronounceable Drugs, Incomprehensible Prices," *Forbes* (Aug. 13, 2014) (online at https://www.forbes.com/sites/matthewherper/2014/08/13/cancer-unpronounceable-drugs-incomprehensible-prices/?sh=6bf5462a27bc).

[6] Ayalew Tefferi, et al., "In Support of a Patient-Driven Initiative and Petition to Lower the High Price of Cancer Drugs," *Mayo Clinic Proceedings*, *90*(8): 996-1000 (July 23, 2015) (online at https://www.mayoclinicproceedings.org/article/S0025-6196%2815%2900430-9/fulltext).

[7] AbbVie acquired Pharmacyclics, including the rights to Imbruvica, in 2015. Following this acquisition, AbbVie continued increasing the price of Imbruvica. See AbbVie, *Press Release: AbbVie to Acquire Pharmacyclics, including its blockbuster product Imbruvica, Creating an Industry Leading Hematological Oncology Franchise* (Mar. 4, 2015) (online at https://news.abbvie.com/news/abbvie-to-acquire-pharmacyclics-including-its-blockbuster-product-imbruvica-creating-an-industry-leading-hematological-oncology-franchise.htm); House Committee on Oversight and Reform, *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* (May 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Committee%20on%20Oversight%20and%20Reform%20-%20AbbVie%20Staff%20Report.pdf).

[8] House Committee on Oversight and Reform, *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* (May 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Committee%20on%20Oversight%20and%20Reform%20-%20AbbVie%20Staff%20Report.pdf).

The story of Imbruvica highlights one of Big Pharma's most profitable strategies: setting the prices for new lifesaving drugs at whatever level they want, regardless of any harm caused to patients.

A launch price is defined as the list price for a drug that has not previously been offered on the market. Recent evidence demonstrates that launch prices are growing at a staggering pace. **From 2008 to 2021, the median launch price for new drugs increased by over 8,000%, from $2,115 to $180,087.**[9] Over this period, the average list price for new medications increased by over 20% per year—more than 10 times the average rate of inflation.[10] In recent months, this troubling trend has accelerated. Recent reporting found that, as of August 2022, the median launch price for 13 new drugs introduced this year is $257,000 — more than three times the median household income for a California family.[11]

There is currently no legal limit to what launch price a pharmaceutical company can set for a new drug. Many drug manufacturers have non-binding pricing principles or other public-facing guidance that purport to offer insights into pricing decisions for their medications. These corporate pricing documents assert that medications should be priced according to their level of innovation and value.[12] But as Congresswoman Porter has exposed in Congressional hearings, the prices for medicines increase even if their clinical benefit remains unchanged.[13]

To address Big Pharma's exploitative pricing practices, Congress passed a law to protect consumers and taxpayers from high pharmaceutical prices. The Inflation Reduction Act (IRA) includes out-of-pocket price caps in Medicare to protect older Americans buying high-cost drugs. Starting in 2025, no older American on Medicare will pay more than $2,000 for prescription drug coverage. The IRA also features limits on insulin spending that will benefit thousands of Californians. In Congresswoman

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[9] Benjamin S. Rome, Alexander C. Egilman, and Aaron S. Kesselheim, "Trends in Prescription Drug Launch Prices, 2008-2021," *Journal of American Medicine,* 327 (1), 2145-2147 (June 7, 2022).
[10] *Id.*
[11] "Newly launched U.S. drugs head toward record-high prices in 2022," *Reuters* (August 16, 2022) (online at https://www.reuters.com/business/healthcare-pharmaceuticals/newly-launched-us-drugs-head-toward-record-high-prices-2022-2022-08-15/); Census Bureau, *California Quick Facts* (online at https://www.census.gov/quickfacts/fact/table/CA/BZA210220) (accessed Sept. 10, 2022).
[12] See, e.g., Sanofi, "Prescription Medicine Pricing: Our Principles and Perspectives," (Aug. 2022) (online at https://www.sanofi.us/en/corporate-responsibility/pricing-principles); Pfizer, "Prescription Value & Pricing" (https://www.pfizer.com/about/programs-policies/prescription-value-and-pricing) (accessed Oct. 2, 2022); GlaxoSmithKline, "Pricing and Access" (online at https://www.gsk.com/en-gb/responsibility/pricing-and-access/) (accessed Oct. 2, 2022); Bristol Myers Squibb, "Pricing" (online at https://www.bms.com/about-us/responsibility/position-on-key-issues/pricing.html) (accessed Oct. 2, 2022); Novo Nordisk, "Our Position on Medicine Pricing" (online at https://www.novonordisk.com/sustainable-business/access-and-affordability/pricing-position.html) (accessed Oct. 2, 2022).
[13] Congresswoman Katie Porter, *Twitter: @RepKatiePorter* (Sept. 30, 2020) (online at https://twitter.com/RepKatiePorter/status/1311374544830070786).

Porter's district alone, an estimated 5,200 Medicare patients will benefit from this provision.[14]

In addition to protecting consumers and making drugs more affordable, the IRA's drug pricing provisions will rein in soaring price increases. Medicare negotiation will drive down costs for medications that have been on the market for at least nine years without competition. Inflation rebates will prevent drugmakers from hiking the prices of medications faster than the rate of inflation.[15] The IRA contains a version of inflation rebates championed by Congresswoman Porter to reduce the price of costly physician-administered medications.[16]

The achievements of the IRA will protect taxpayers from the burdens high-cost drugs impose on our health system and will help patients afford the drugs they need. But to maximize these reforms, Congress must target the pharmaceutical strategy that continues to exploit patients and taxpayers: launching new products at astronomical prices. Pharmaceutical manufacturers have increased drug launch prices because they can, boosting their bottom lines at the expense of patients and taxpayers. Few legislative solutions have been proposed for launch prices, a central pricing strategy for Big Pharma.

The next frontier in the battle to lower drug costs is launch prices. Big Pharma has failed to list new products at responsible prices, and pharmacy benefit managers (PBMs) have used high list prices as a cover to extract rebates from manufacturers with minimal transparency. This report analyzes the soaring launch prices and high costs of an important subset of drugs—self-administered cancer medications[17]—both to expose the harm high drug prices cause to patients, and to chart a path forward for future reforms.

[14] White House, "The Inflation Reduction Act Will Cut Health Care Costs for Californians" (Aug. 4, 2022) (online at https://www.whitehouse.gov/wp-content/uploads/2021/08/CALIFORNIA_The-Infrastructure-Investment-and-Jobs-Act-State-Fact-Sheet.pdf).
[15] See P.L. 117-169, The Inflation Reduction Act (online at https://www.congress.gov/bill/117th-congress/house-bill/5376/text), signed into law by President Biden on August 16, 2022.
[16] Office of Congresswoman Katie Porter, *Press Release: Rep. Porter Spearheads Legislation to Crack Down on Big Pharma Price Hikes* (Apr. 20, 2021) (online at https://porter.house.gov/news/documentsingle.aspx?DocumentID=342).
[17] Unless otherwise noted, the data contained in this report are limited to chemical drugs and therapeutic biologic cancer medications regulated by the Center for Drug Evaluation and Research and administered under Medicare Part D.

III. The Soaring Launch Prices of Cancer Drugs

Cancer drugs represent some of the most urgent, innovative interventions in health care. With nearly two million Americans receiving cancer diagnoses each year,[18] the pharmaceutical industry understands the economic benefit of investing in cancer therapies. IQVIA, a pharmaceutical industry research company, reports that oncology therapies lead all other therapy areas in terms of "level of clinical trial activity, number of companies investing in therapeutics, size of the pipeline of therapies in clinical development, novel active substances being launched, and the level of expenditure on these drugs."[19]

Unsurprisingly, the level of clinical activity and investment mirror rapid increases in cancer drug revenues. Between 2010 and 2019, the annual revenue generated by cancer drugs increased by 96%, while the revenue from non-oncology drugs decreased.[20]

Revenues from cancer medications deserve special scrutiny because the launch prices of oncology medications typically far exceed non-oncology drugs. A recent study of launch prices between 2008 and 2021 found that the launch prices of oncology drugs are 3.7 times higher than those of non-oncology drugs.[21]

As lawmakers have considered and implemented policy solutions to limit the price increases applied to prescription drugs, pharmaceutical manufacturers have significantly increased launch prices for new cancer drugs. Figure 1 shows the launch prices for newly approved cancer drugs in 2017 and 2021. (For a detailed description of methods and sources, see Appendix A.)

[18] National Cancer Institute, National Institutes of Health, *Cancer Stat Facts: Common Cancer Sites* (online at https://seer.cancer.gov/statfacts/html/common.html) (accessed Sept. 8, 2022).
[19] IQVIA, *Global Oncology Trends 2022* (May 26, 2022) (online at https://www.iqvia.com/insights/the-iqvia-institute/reports/global-oncology-trends-2022).
[20] Daniel E. Meyers, et al., "Temporal Trends in Oncology Drug Revenue Among the World's Major Pharmaceutical Companies: A 2010-2019 Cohort Study," Journal of Clinical Oncology, 39(15): 6505-6505 (May 28, 2021) (online at https://ascopubs.org/doi/10.1200/JCO.2021.39.15_suppl.6505).
[21] Benjamin S. Rome, Alexander C. Egilman, and Aaron S. Kesselheim, "Trends in Prescription Drug Launch Prices, 2008-2021," *Journal of American Medicine*, 327 (1), 2145-2147 (June 7, 2022).

Figure 1: Launch Prices for Self-Administered Cancer Drugs, 2017 and 2021

2017				2021			
Name	Date	Cancer type	Launch Price ($)	Name	Date	Cancer type	Launch Price ($)
Calquence	10/31/2017	Lymphoma	184,327	Besremi	11/12/2021	Blood Cancer	182,000
Verzenio	9/28/2017	Breast Cancer	141,515	Scemblix	10/29/2021	Leukemia	214,800
Idhifa	8/1/2017	Leukemia	321,501	Exkivity	9/15/2021	Lung Cancer	299,995
Rydapt	4/28/2017	Leukemia	209,911	Truseltiq	5/28/2021	Cholangiocarcinoma	258,000
Alunbrig	4/28/2017	Lung Cancer	184,198	Lumakras	5/28/2021	Lung Cancer	214,800
Zejula	3/27/2017	Ovarian Cancer	127,108	Fotivda	3/10/2021	Renal Cell Carcinoma	289,900
Kisqali	3/13/2017	Breast Cancer	153,336	Ukoniq	2/5/2021	Lymphoma	190,800
				Tepmetko	2/3/2021	Lung Cancer	250,775
		AVERAGE	188,842			AVERAGE	237,634
		MEDIAN	188,842			MEDIAN	232,788

Between 2017 and 2021, the inflation-adjusted average launch prices for self-administered cancer drugs increased by 25.8%. If launch prices continue to increase at the average annual rate for this period, the average new cancer medication will cost over $300,000 by 2025.[22] Median launch prices of self-administered cancer drugs increased by 23.2%. The 2021 median oncology drug launch price of $232,788 is roughly 2.5 times the median household income for an Orange County family.[23]

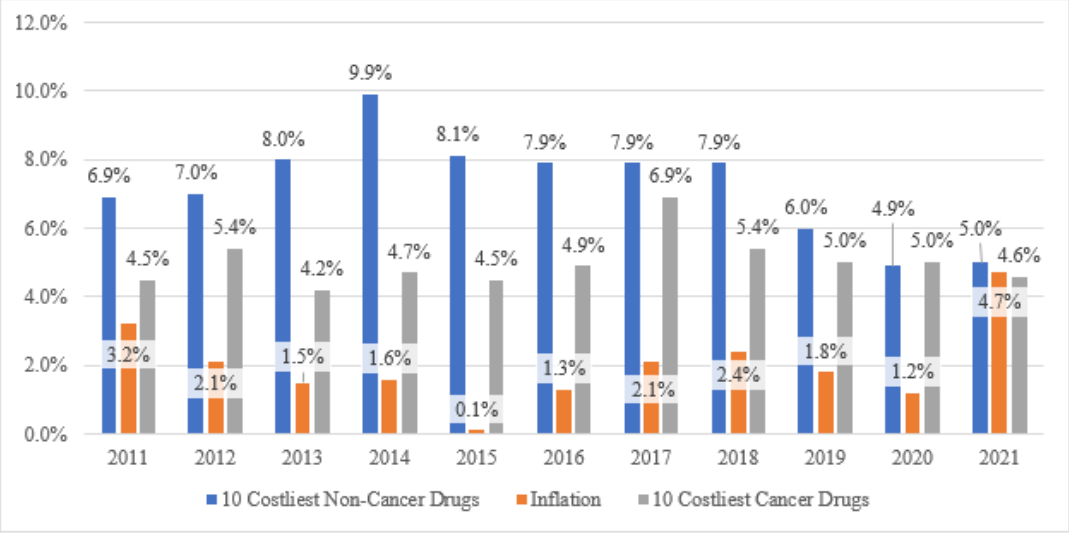
Expanding the analysis beyond self-administered cancer medications alone reveals even more stark launch price increases. Our office calculated launch price trends for the drugs and therapeutic biologics regulated by the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER)[24], including drugs

[22] This figure was calculated by dividing the average launch price percent increase from 2017 to 2021 and dividing by the number of years of launch price increases (four years) to arrive at an average year-over-year launch price increase percentage. The year-over-year increase was multiplied by the 2021 average launch price to arrive at the 2022 average launch price, and was repeated for each year through 2025.
[23] Census Bureau, *Orange County, California Quick Facts* (online at https://www.census.gov/quickfacts/orangecountycalifornia) (accessed Sept. 10, 2022).
[24] Due to difficulties in locating and calculating accurate annualized pricing data, therapies regulated by FDA's Center for Biologics Evaluation and Research (CBER) were excluded from this analysis. The lack of a centralized, public

administered as infusions. **For this subset of drugs, the average annual price of cancer therapies increased from approximately $185,000 in 2017 to over $283,000 in 2021—a 53.0% increase.** (For a detailed description of methods and sources, see Appendix B.)

Even after setting high launch prices, drugmakers take regular price increases on these medications, forcing patients to pay even more for medications. But price increases alone account for neither the prohibitive costs of oncology medications, nor the growing share of drug revenue attributable to them. As demonstrated in Figure 2 below, the ten costliest cancer drugs to the Medicare program have seen lower price increases than the ten costliest drugs in other classes.[25]

Figure 2: Comparison of Median Drug Price Increases with Inflation Rate for 10 Costliest Cancer and Non-Cancer Drugs[26]



As evidenced by these data, for the costliest drugs to the Medicare program, price increases across all drug classes have increased faster than the rate of inflation. But for ten of the eleven years analyzed, prices for the costliest non-cancer drugs increased at a higher rate than the costliest cancer drugs. **High-cost cancer drugs**

database with key launch price data highlights the need for manufacturers to publicly disclose the list prices for their pharmaceutical products.

[25] For the list of ten cancer medications that were costliest to Medicare, please see: Stacie B. Dusetzina, "Your Money or Your Life – The High Cost of Cancer Drugs under Medicare Part D," *New England Journal of Medicine, 386*: 2164-2167 (June 9, 2022). For the list of other drugs, please see Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard & Data* (online at www.cms.gov/ResearchStatistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD) (accessed Oct. 2, 2022).

[26] 46Brooklyn, *Brand Drug List Price Change Box Score: Box Stat #3: Median Percentage WAC Increase on Brand Name Drugs* (online at https://www.46brooklyn.com/branddrug-boxscore) (accessed Sept. 9, 2022); Bureau of Labor Statistics, Department of Labor, *CPI Inflation Calculator* (online at https://www.bls.gov/data/inflation_calculator.htm) (accessed Sept. 9, 2022).

comprise a growing share of total drug sales but have lower annual price increases than non-cancer drugs. This suggests that other pricing practices—namely, high launch prices—are driving revenue growth in the oncology sector. To better protect patients with cancer from Big Pharma's unreasonable and unfair pricing practices, policymakers must target launch prices in addition to price increases.

IV. The Disproportionate Harm of High Launch Prices

Prohibitively high drug prices leave many patients with cancer unable to afford their medications—even for patients with insurance. The expected average annual out-of-pocket cost per cancer prescription nearly doubled from approximately $7,400 to almost $14,000 between 2010 and 2019.[27]

As out-of-pocket costs for medications increase, cancer patients are more likely to delay or entirely forego filling prescriptions for drugs they need.[28] According to a 2022 study, 28.3% of Medicare patients failed to fill cancer drugs newly prescribed by their doctors.[29]

But not all patients experience the same harm from high drug prices. Based on the type of insurance a patient has—or whether a patient has insurance at all—drugs with high launch prices may be entirely unaffordable.

Certain patients, like the 26.4 million Americans who lack insurance, [30] may be forced to pay the entire amount of a drug's list price without assistance, which can be a prohibitive amount for nearly any person or family.

But for the 21% of underinsured Americans who face overwhelming out-of-pocket health costs, insurance coverage alone does not necessarily protect patients from high prescription drug prices.[31] Depending on patients' cost sharing arrangements with

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[27] Stacie B. Dusetzina, et al., "Specialty Drug Pricing and Out-of-Pocket Spending on Orally Administered Anticancer Drugs in Medicare Part D, 2010 to 2019," *JAMA*, *321*(20): 2025-2028 (May 28, 2019) (online at https://jamanetwork.com/journals/jama/fullarticle/2734308).
[28] Jalpa A. Doshi, et al., "Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents," *Journal of Clinical Oncology, 36* (5), 476-482 (Feb. 10, 2018).
[29] Stacie B. Dusetzina, et al., "Many Medicare Beneficiaries Do Not Fill High Price Specialty Drug Prescriptions," *Health Affairs 41* (4): 487-496 (Apr. 2022).
[30] Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, *National Uninsured Rate Reaches All-Time Low in Early 2022* (August 2, 2022) (online at https://www.aspe.hhs.gov/sites/default/files/documents/77ba3e9c99264d4f76dd662d3b2498c0/aspe-ib-uninsured-aca.pdf?_ga=2.30933436.28268287.1660934780-157263427.1660934780).
[31] Commonwealth Fund, "U.S. Health Insurance coverage in 2020: A Looming Crisis in Affordability" (Aug. 19, 2020) (online at https://www.commonwealthfund.org/publications/issue-briefs/2020/aug/looming-crisis-health-coverage-2020-biennial). The Commonwealth Fund considers "people who are insured all year to be underinsured if: (a) their out-of-pocket costs, excluding premiums, over the prior 12 months are equal to 10 percent or more of

their insurers, certain individuals may experience higher out-of-pocket costs for high-priced medicines.

Among insured patients, cost sharing may take the form of copays (flat fees), coinsurance (a percentage of the drug's price), or deductibles (paying full price until you reach a specified level of spending). Depending on the plan's benefit design, some insured Americans may be responsible for paying a portion or all of a drug's list price. For patients taking drugs that cost hundreds of thousands of dollars, coinsurance payments representing even a small percentage of the list price could lead to out-of-pocket costs that are too expensive to afford. For example, as demonstrated in Figure 3 below, a Medicare patient who is responsible for paying 5% of a drug's list price after maxing out their prescription drug benefit will pay over $800 per month for a cancer drug priced at $16,000 per month.

Even when patients have insurance with an out-of-pocket cap, the total expenditures for drugs may be too high to afford. For example, patients who have high deductible health plans may reach their annual deductible with a single fill of a high-cost prescription, leaving them with a potentially unaffordable bill due all at once.

Ultimately, patients without flat copayments who must pay all or part of the drug's list price—including Medicare patients—experience the most harm from high launch prices. Prior studies show that for Medicare Part D patients needing high-priced cancer drugs, nearly every fill requires patients to pay all or part of the list price.[32] When the prices for their drugs go up, so do their out-of-pocket expenses. A recent study found that among the 53.7% of patients who paid drug deductibles or coinsurance, median out-of-pocket spending increased at nearly the same rate as drug list prices—a finding not observed in patients paying flat-fee copayments.[33] These patients experience unique harms from drugs with high launch prices.

Patients who face high out-of-pocket bills are significantly less likely to receive their medications, as high rates of unfilled prescriptions are directly correlated with patient out-of-pocket costs. Similarly, Medicare patients who have subsidies that lower their out-of-pocket costs are more likely to fill their prescriptions than those with higher

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household income; (b) their out-of-pocket costs, excluding premiums, over the prior 12 months are equal to 5 percent or more of household income for individuals living under 200 percent of the federal poverty level ($25,520 for an individual or $52,400 for a family of four in 2020); or (c) their deductible constitutes 5 percent or more of household income."

[32] Stacie B. Dusetzina and Nancy L. Keating, "Mind the Gap: Why Closing the Doughnut Hole Is Insufficient for Increasing Medicare Beneficiary Access to Oral Chemotherapy," *Journal of Clinical Oncology*, 34 (4): 375-380 (Dec. 7, 2015) (online at https://pubmed.ncbi.nlm.nih.gov/26644524/).

[33] Benjamin N. Rome, et al., "Correlation Between Changes in Brand-Name Drug Prices and Patient Out-of-Pocket Costs," *JAMA Network Open*, 4 (5): 218816 (May 4, 2021) (online at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2779442).

out-of-pocket expenses, even if they have very low incomes. For example, Medicare Part D patients receiving low-income subsidies, who pay as little as $10 for one month's supply of drugs, were 35% more likely to fill prescriptions for cancer drugs that can cost other Medicare cancer patients nearly $4,000 for a single month's supply.[34]

While new out-of-pocket spending caps will be implemented in the coming years, there is currently no limit to what Medicare Part D patients spend on prescription drugs. For years, the benefit design of Medicare's prescription drug coverage has exposed patients to high costs. Currently, patients who max out their Part D prescription drug benefit and enter catastrophic coverage are responsible for 5% of the list price of a drug.[35] Even though it may seem reasonable to limit the beneficiary obligation to 5% of a drug's list price, drugs with very high list prices, like cancer drugs, can leave patients paying thousands of dollars out-of-pocket even after they have reached the catastrophic phase of Part D coverage.

A patient's ability to afford their medication should not dictate whether they receive lifesaving care. Thankfully, the IRA will protect Medicare patients from prohibitive costs associated with high priced drugs. Starting in 2024, as part of the Inflation Reduction Act, patients will no longer be required to pay 5% of a drug's list price in the catastrophic phase. In 2025, Medicare Part D patients will have a base out-of-pocket cap for the first time, limiting expenditures for all patients to $2,000 per year.

Hundreds of thousands of older adults and people with disabilities will benefit from this cap on spending. In 2020, more than 1.4 million Medicare patients exceeded $2,000 in out-of-pocket drug spending.[36] The benefits of a $2,000 cap may reach even more Americans, as many Medicare patients spent less than $2,000 on drugs because they could not afford to fill all their prescriptions.[37]

Patients taking high-cost drugs, including cancer drugs, will save thousands of dollars per year because of the out-of-pocket spending cap. Take, for example,

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[34] Stacie B. Dusetzina, et al., "Many Medicare Beneficiaries Do Not Fill High Price Specialty Drug Prescriptions," *Health Affairs 41* (4): 487-496 (Apr. 2022).
[35] The Medicare Part D benefit design features four different phases of payments, based on the amount spent on medications within a plan year. First, in the deductible phase, the beneficiary is responsible for the full cost of the medication. Second, in the initial coverage phase, the beneficiary is responsible for 25% of the list price of the drug. Once total spending—combining the contributions of the patient, the insurer (also known as a Part D plan or plan sponsor), and the government—reaches a certain spending threshold (equal to $7,050 in 2022), the beneficiary enters "catastrophic coverage" and is responsible for five percent of the list price.
[36] Kaiser Family Foundation, "How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare Beneficiaries?" (Aug. 18., 2022) (online at https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/).
[37] Stacie B. Dusetzina, et al., "Many Medicare Beneficiaries Do Not Fill High Price Specialty Drug Prescriptions," *Health Affairs 41* (4): 487-496 (Apr. 2022).

Medicare patients taking the oral cancer drug Imbruvica. Nearly 27,000 Medicare Part D patients filled Imbruvica prescriptions in 2020, the most recent year for which data are available.[38] The federal government spent more than $110,000 covering the drug for each of these beneficiaries, on average. [39]

Today, the price of a single 140mg capsule of Imbruvica is $178.[40] A patient taking a regular course of Imbruvica typically requires three capsules per day, bringing the price of a monthly regimen of Imbruvica to $16,020 and the annualized cost to $192,240.[41] A Medicare Part D beneficiary filling prescriptions for Imbruvica today would not only meet their deductible with a single fill—they would enter into catastrophic coverage and still be responsible for hundreds of dollars of costs.

For a single year's supply of Imbruvica, Figure 3 shows the financial obligation of a patient, insurance plan, manufacturer, and the Medicare program, based on the current Medicare Part D standard benefit.[42]

[38] Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard & Data* (online at www.cms.gov/ResearchStatistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD) (accessed Oct. 2, 2022).
[39] *Id.*
[40] In 2021, the price of a single 140mg pill for Imbruvica cost $165.77. On January 14, 2022, AbbVie increased the price of Imbruvica by 7.4%, leading to a calculated list price of $178.04. House Committee on Oversight and Reform, *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* (May 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Committee%20on%20Oversight%20and%20Reform%20-%20AbbVie%20Staff%20Report.pdf); 46Brooklyn, *Brand Drug List Price Change Box Score* (online at https://www.46brooklyn.com/branddrug-boxscore) (accessed Aug. 16, 2022).
[41] Patients may also take a single 420mg dose orally. AbbVie prices Imbruvica by the milligram of active ingredient, meaning there is no meaningful difference between the cost of three 140-mg capsules and one 420-mg tablet.
[42] While the analyses in Figure 3 and Figure 4 exclude any rebates offered by the manufacturer, which shift obligations from the plan to the manufacturer, the evidence suggests that manufacturers offer minimal rebates to Part D plans for cancer drugs. See Thomas J. Hwang, et al., "Assessment of Out-of-Pocket Costs with Rebate Pass-through for Brand-name Cancer Drugs Under Medicare Part D," *JAMA Oncology, 8* (1): 155-156 (Jan. 2022).

Figure 3: Total Spending on an Annual Course of Imbruvica Based on the 2022 Part D Benefit Design

	Price	Patient	Plan	Manufacturer	Medicare Reinsurance
January	$ 16,020	$ 3,222	$ 4,113	$ 4,113	$ 4,571
February	$ 16,020	$ 801	$ 2,403	$ 0	$ 12,816
March	$ 16,020	$ 801	$ 2,403	$ 0	$ 12,816
April	$ 16,020	$ 801	$ 2,403	$ 0	$ 12,816
May	$ 16,020	$ 801	$ 2,403	$ 0	$ 12,816
June	$ 16,020	$ 801	$ 2,403	$ 0	$ 12,816
July	$ 16,020	$ 801	$ 2,403	$ 0	$ 12,816
August	$ 16,020	$ 801	$ 2,403	$ 0	$ 12,816
September	$ 16,020	$ 801	$ 2,403	$ 0	$ 12,816
October	$ 16,020	$ 801	$ 2,403	$ 0	$ 12,816
November	$ 16,020	$ 801	$ 2,403	$ 0	$ 12,816
December	$ 16,020	$ 801	$ 2,403	$ 0	$ 12,816
TOTAL $	$ 192,240	$ 12,033	$ 30,546	$ 4,113	$ 145,547
TOTAL %		6.2%	15.8%	2.1%	75.7%

The current standard Part D benefit requires Imbruvica patients to pay over $12,000 for the drugs they need to survive for each full year they take the medicine. Among patients taking Imbruvica for the median treatment duration of 27 months, out-of-pocket costs could total nearly $29,000.[43] The federal government is responsible for a vast majority of these costs through Medicare reinsurance payments–the Part D subsidies that come directly from the Medicare program.[44]

[43] Maria Winqvist, et al., "Long-term Real-world Results of Ibrutinib Therapy in Patients with Relapsed or Refractory Chronic Lymphocytic Leukemia: 30-month Follow Up of the Swedish Compassionate Use Cohort," *Haematologica, 104* (5): e208-e210 (May 2019) (online at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6518914/).
[44] Kaiser Family Foundation, "An Overview of the Medicare Part D Prescription Drug Benefit" (Oct. 13, 2021) (https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/).

The new Part D standard benefit design, which will be in place in 2025, places a $2,000 limit on patient out-of-pocket expenditures and changes the percentage of costs paid by plans, manufacturers, and the Medicare program. Based on recently enacted changes in the Inflation Reduction Act, Figure 4 shows what the same annual prescription of Imbruvica would cost a patient, an insurance plan, a manufacturer, and Medicare if the Part D benefit redesign had already taken effect.

Figure 4: Total Spending on an Annual Course of Imbruvica Based on the Inflation Reduction Act Part D Benefit Redesign

	Price	Patient	Plan	Manufacturer	Medicare Reinsurance
January	$ 16,020	$ 2,000	$ 9,628	$ 2,500	$ 1,892
February	$ 16,020	$ 0	$ 9,612	$ 3,204	$ 3,204
March	$ 16,020	$ 0	$ 9,612	$ 3,204	$ 3,204
April	$ 16,020	$ 0	$ 9,612	$ 3,204	$ 3,204
May	$ 16,020	$ 0	$ 9,612	$ 3,204	$ 3,204
June	$ 16,020	$ 0	$ 9,612	$ 3,204	$ 3,204
July	$ 16,020	$ 0	$ 9,612	$ 3,204	$ 3,204
August	$ 16,020	$ 0	$ 9,612	$ 3,204	$ 3,204
September	$ 16,020	$ 0	$ 9,612	$ 3,204	$ 3,204
October	$ 16,020	$ 0	$ 9,612	$ 3,204	$ 3,204
November	$ 16,020	$ 0	$ 9,612	$ 3,204	$ 3,204
December	$ 16,020	$ 0	$ 9,612	$ 3,204	$ 3,204
TOTAL $	$ 192,240	$ 2,000	$ 115,360	$ 37,744	$ 37,136
CHANGE $ from CURRENT		$ -10,033	$ +84,184	$ +33,631	$ -108,411
TOTAL %		1.0%	60.0%	19.6%	19.3%
CHANGE % from CURRENT		-5.2%	+44.2%	+17.5%	-56.2%

According to this example, a $2,000 out-of-pocket cap could save a Medicare patient taking high-cost cancer drugs over $10,000 per year.[45] **For a patient taking the typical Imbruvica course of 27 months, costs would not exceed $6,000—putting up to $23,000 back into patients' pockets, according to our office's calculations.** To further ease the burden of high-out-of-pocket costs and encourage patients to fill the

[45] Stacie B. Dusetzina, "Your Money or Your Life – The High Cost of Cancer Drugs under Medicare Part D," *New England Journal of Medicine, 386*: 2164-2167 (June 9, 2022).

prescriptions they need, the Inflation Reduction Act allows patients to distribute the $2,000 payment over the remaining months in the year.[46] For example, a patient who enrolls in a "cost smoothing" option at the beginning of the year could pay the $2,000 in monthly payments of less than $200 instead of paying in one lump sum. In addition, the new Part D benefit redesign will reduce the amount taxpayers pay for high-cost drugs through Medicare reinsurance rates.

For years, the standard design of Medicare prescription drug insurance—which currently includes coinsurance and no out-of-pocket cap—has exposed older adults and disabled Americans to enormous and unlimited out-of-pocket costs for high-priced drugs. Through the Inflation Reduction Act, Congress has taken significant steps to help Medicare patients afford the drugs they need. As the American population ages, Congress has started to fulfill its promise to protect patients from the corporate greed of Big Pharma.

V. High-Cost Cancer Drugs and Medicare

Because cancer is more common among older Americans, cancer care is central to Medicare coverage.[47] Medicare patients are more likely to receive cancer diagnoses than other populations. According to the National Cancer Institute, advancing age is the most important risk factor for cancer.[48] The median age for cancer diagnoses is 66 years old, at which point an individual is already eligible for Medicare.[49]

Furthermore, because many uninsured and underinsured Americans delay seeking regular preventive care until they are enrolled in Medicare coverage, cancer diagnoses increase after age 65. For example, colon cancer diagnoses—typically detected by colonoscopies that are a regular part of preventive care for older Americans with insurance—are seven times more likely to occur at age 65, when individuals first enroll in Medicare, as compared to ages 61-64.[50]

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[46] Kaiser Family Foundation, "Explaining the Prescription Drug Provisions in the Inflation Reduction Act" (Sept. 22, 2022) (online at https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/).
[47] Centers for Medicare & Medicaid Services, *Medicare Part D Spending by Drug* (online at https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug) (accessed Sept. 8, 2022).
[48] National Cancer Institute, National Institutes of Health, *Age and Cancer Risk* (online at https://www.cancer.gov/about-cancer/causes-prevention/risk/age) (accessed Sept. 8, 2022).
[49] *Id.*
[50] Deven C. Patel, et al., "Cancer Diagnoses and Survival Rise as 65-year-olds Become Medicare-Eligible," *Cancer* 127 (3): 2302-2310 (Mar. 29, 2021).

Because many patients with cancer receive coverage through Medicare, cancer drugs are punishingly expensive to the taxpayers that fund the Medicare program. Oncology drugs consistently rank among the costliest drugs to the Medicare program, even though each drug is taken by a relatively low number of patients.

Compared with other high-spending drugs that cost Medicare billions of dollars, cancer drugs reach a significantly smaller number of patients. Figure 5 shows the total spending and the number of patients for the ten costliest drugs to the Medicare program in 2020.

Figure 5: Total Spending and Number of Medicare Patients for the Ten Costliest Medicare Part D Drugs, 2020

Drug Name	Drug Type	Total Medicare Spending	Total Medicare Patients
Eliquis	Blood Thinner	$9,936,069,813.70	2,641,941
Revlimid	Cancer	$5,356,050,274.60	43,747
Xarelto	Blood Thinner	$4,701,314,805.00	1,184,718
Januvia	Diabetes	$3,865,087,772.50	934,686
Trulicity	Diabetes	$3,284,873,061.90	497,327
Imbruvica	Cancer	$2,962,909,303.60	26,847
Lantus Solostar	Insulin	$2,663,360,231.80	1,002,500
Jardiance	Diabetes	$2,376,166,292.40	594,859
Humira	Anti-Inflammatory	$2,169,430,424.10	42,406
Ibrance	Cancer	$2,108,937,188.30	21,394

Among the ten costliest drugs to the Medicare system listed above, the average non-cancer drug reaches more than 985,000 patients compared to just over 30,000 for cancer drugs. Put another way, the costliest non-cancer drugs reach 32 times as many patients as the costliest cancer drugs.

Because pharmaceutical companies set irresponsible prices for drugs, each cancer prescription represents a significant financial burden. Outside of drugs for rare diseases that treat a very small number of patients (fewer than 5,000 Medicare beneficiaries per year), oncology treatments rank among the costliest therapies per Medicare patient. **In 2020, only five drugs were prescribed to more than 5,000**

Medicare patients with an average cost per patient greater than $110,0000. All of them were cancer drugs.[51] Figure 6 shows the average Medicare spending per patient for these five cancer medications.[52]

Figure 6: Five Most Expensive Drugs Per Patient in Medicare Part D, 2020 (min. 5,000 patients)

Drug Name	2020 Medicare Spending	Total Patients	Average Spent Per Patient
Revlimid	$5,356,050,274.60	43,747	$122,432.40
Pomalyst	$1,453,860,766.50	12,067	$120,482.37
Jakafi	$1,296,674,522.10	11,361	$114,133.84
Tagrisso	$793,479,171.97	7,016	$113,095.66
Imbruvica	$2,962,909,303.60	26,847	$110,362.77

The harm that Big Pharma's high-cost cancer drugs cause to patients is evident. But these soaring drug prices also force the Medicare system to assume excessive costs to deliver care for each cancer patient. Lowering cancer drug prices—including launch prices—would prevent pharmaceutical companies from extorting patients and taxpayers for lifesaving drugs. High-cost drugs, like cancer medications, drive Medicare prescription drug spending. In 2019, the Part D program spent approximately $87 billion—roughly 60% of its total expenditures—on just 7% of the prescription drugs filled by seniors.[53]

Unlike other high-cost drugs, like diabetes therapies or blood thinners, the pharmaceutical industry provides minimal rebates for cancer drugs.[54] This means taxpayers and patients are forced to pay almost all of a drug's price without

[51] Centers for Medicare & Medicaid Services, *Medicare Part D Spending by Drug* (online at https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug) (accessed Sept. 8, 2022).
[52] *Id.*
[53] Relatively Few Drugs Account for a Large Share of Medicare Prescription Drug Spending," *Kaiser Family Foundation* (Apr. 19, 2021) (online at https://www.kff.org/medicare/issue-brief/relatively-few-drugs-account-for-a-large-share-of-medicare-prescription-drug-spending/).
[54] Thomas J. Hwang, et al., "Assessment of Out-of-Pocket Costs with Rebate Pass-through for Brand-name Cancer Drugs Under Medicare Part D," *JAMA Oncology, 8* (1): 155-156 (Jan. 2022).

meaningful discounts from manufacturers. Though the IRA will force drugmakers to contribute more discounts, taxpayers will still be forced to pay a significant amount for high-priced drugs through premiums for Part D plans and Medicare reinsurance—particularly if the costs of new cancer medications continue to rise.[55]

Because many cancer drugs treat only one or a handful of indications at the time of their launch, some contend that the low number of patients who are eligible for particular cancer treatments, combined with the level of innovation and clinical benefit, justifies astronomical prices for cancer drugs.[56] Yet this argument fails to acknowledge that, as pharmaceutical companies invest in research to uncover additional indications for their medications and patient bases expand, prices do not fall. Instead, when pharmaceutical companies find additional uses for their drugs, they jack up prices even faster.[57]

In 2020, Congresswoman Katie Porter questioned a former pharmaceutical CEO, Mark Alles, whose company tripled the price of the cancer drug Revlimid since its introduction in 2005.[58]

[55] Congressional Budget Office, *Estimated Budgetary Effects of H.R. 5376, the Inflation Reduction Act of 2022* (Aug. 3, 2022) (online at https://www.cbo.gov/publication/58366); Letter from Phillip L. Swagel, Director, Congressional Budget Office, to The Honorable Jason Smith, Ranking Member, House Committee on Budget (Aug. 4, 2022) (online at https://www.cbo.gov/system/files/2022-08/58355-Prescription-Drug.pdf).
[56] *See, e.g.*, PhRMA, "Why Are Cancer Medicines Expensive?" (Oct. 6, 2014) (online at https://catalyst.phrma.org/why-are-cancer-medicines-expensive).
[57] Caroline S. Bennette, "Steady Increase in Prices for Oral Anticancer Drugs after Market Launch Suggests a Lack of Competitive Pressure," *Health Affairs, 35* (5) (May 2016) (online at https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1145).
[58] House Committee on Oversight and Reform, *Hearing: Unsustainable Drug Prices: Testimony from the CEOs (Part I)* (Sept. 30, 2020) (online at https://docs.house.gov/meetings/GO/GO00/20200930/111055/HHRG-116-GO00-Transcript-20200930.pdf).

Rep. PORTER: And today, Revlimid costs $763 per pill. I am curious. Did the drug get substantially more effective in that time? Did cancer patients need fewer pills?

Mr. ALLES: During that time, the development of Revlimid included six additional indications, some in lymphoma and the balance in patients with different segments of multiple myeloma.

Rep. PORTER: Reclaiming my time. So, Mr. Alles, you discovered more patients who might benefit from paying $763 a pill, but being able to use the drug for more patients doesn't necessarily [require] more price. Did the drug start to work faster? Were there fewer side effects? How did you change the formula or production of Revlimid to justify this price increase?

Mr. ALLES: The indication changes are for subsets of different patients with disease.

Rep. PORTER: Reclaiming my time. Mr. Alles, I understand that. What I am trying to understand from you is how did the drug improve? If I were to look at a pill and analyze it from 2005, when it cost $215, and I looked today when it costs $763, would that pill be the same?

Mr. ALLES: I understand your question about the pill. The pill, the manufacturing for it, would be the same.

Rep. PORTER: Right. Thank you. So, to put that in perspective, you hiked the price by $500, when the average Orange County senior only has $528 left in their bank account after they have paid their basic monthly expenses. The average Orange County senior can't even afford one pill.

In his response, Mr. Alles suggests that finding additional patients to take Revlimid actually increased the drug's value, justifying further price increases. The practice of raising drug prices after finding additional indications generates additional concerns given the soaring launch prices of oncology drugs. Should manufacturers follow this practice, price increases will put already expensive products even further out of reach.

Since this hearing, Revlimid's manufacturer has increased its price by 4.5% in each of the last two years.[59]

VI. Targeting Launch Prices Will Maximize Drug Pricing Reforms

The Inflation Reduction Act is a transformational policy victory for patients and taxpayers. But the work to make drug prices affordable is just getting started. Congress must address pharmaceutical launch prices to maximize the benefits of recently enacted drug pricing reforms.

Through the Inflation Reduction Act, Congress and the Biden Administration have taken significant steps to help patients afford their prescription drugs and rein in

[59] 46Brooklyn, *Brand Drug List Price Change Box Score: Box Stat #3: Median Percentage WAC Increase on Brand Name Drugs (Search Term: Revlimid Oral Capsule)* (online at https://www.46brooklyn.com/branddrug-boxscore) (accessed Sept. 9, 2022); "Drugmakers Kick Off 2021 with 500 U.S. Price Hikes," Reuters (Jan. 4, 2021) (online at https://www.reuters.com/article/us-usa-healthcare-drugpricing/drugmakers-kick-off-2021-with-500-u-s-price-hikes-idUSKBN2992IY).

soaring drug prices. Starting in 2025, for the first time, 5.1 million California Medicare patients will have the comfort of knowing that they will spend no more than $2,000 on the prescription drugs they need to stay healthy.[60] The out-of-pocket cap will directly benefit 114,800 Californians who otherwise would have spent more—and in some cases, many thousands of dollars more—on medications.[61]

Policy tools like inflation rebates—which penalize manufacturers for raising drug prices higher than the rate of inflation—will keep costs affordable for drugs that are currently on the market. For example, Congresswoman Porter introduced the *Freedom from Price Gouging Act* to require manufacturers to pay a penalty for drugs with prices that increased faster than the rate of inflation.[62] A version of this provision was included in the Inflation Reduction Act, signed into law by President Biden on August 16, 2022.

Importantly, the benefits of inflation rebates may extend beyond the Medicare program, alone. A recent analysis found that the spillover effects from Medicare inflation rebates could reduce private insurance spending by $31 billion over the next decade and save $8 billion in out-of-pocket costs for privately insured patients.[63]

The Inflation Reduction Act will finally empower the Medicare program to negotiate fair prices for a subset of medications nearing the end of their patent protection periods. Like public health systems in peer nations, the government will use access to its market of millions of patients to secure savings for patients and taxpayers. Unlike health systems in other nations, however, the number and type of drugs eligible for negotiation will be limited.

Starting in 2026, Medicare will be able to negotiate 10 Part D drugs, expanding to 20 drugs per year from Parts B and D by 2029. Drugs must be among the costliest drugs to the Medicare program, have no generic competition, and must have been on the market for either nine or thirteen years, depending on the type of drug, along with several other minor exceptions.

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[60] White House, "The Inflation Reduction Act Will Cut Health Care Costs for Californians" (Aug. 4, 2022) (online at https://www.whitehouse.gov/wp-content/uploads/2022/08/California-Health-Care.pdf).
[61] *Id.*
[62] Office of Congresswoman Katie Porter, *Press Release: Rep. Porter Spearheads Legislation to Crack Down on Big Pharma Price Hikes* (Apr. 20, 2021) (online at https://porter.house.gov/news/documentsingle.aspx?DocumentID=342).
[63] Council for Informed Drug Spending Analysis, *Commercial Savings Generated by Spillover from Medicare Inflation Penalties Under the Inflation Reduction Act of 2022* (Sept. 8, 2022) (online at https://www.cidsa.org/publications/commercial-savings-generated-by-spillover-from-medicare-inflation-penalties-under-the-inflation-reduction-act-of-2022).

Ending the prohibition on Medicare negotiation will finally let Medicare secure fair prices for high-cost medicines. By 2029, up to 60 high-cost drugs will be eligible for negotiation, which could reach as many as five to seven million Part D patients.[64]

Altogether, the benefits of the Inflation Reduction Act would not only improve the health of older Americans and individuals with disabilities—they will save billions of dollars that would otherwise boost Big Pharma's bottom lines. Two key provisions alone—the inflation rebates and Medicare negotiation—are projected to save approximately $200 billion in government spending over the next ten years.[65]

However, inflation rebates alone may not completely solve the problem of excessive drug prices if pharmaceutical manufacturers continue increasing the launch prices for new products. Some health policy experts project that recently enacted reforms could even apply upward pressure on launch prices, writing: "It would be extraordinary for pharmaceutical companies not to take this opportunity to push U.S. drug launch prices to even higher levels."[66]

It is important to note that there is disagreement among drug pricing experts as to whether launch prices will accelerate following the Inflation Reduction Act. The idea that pharmaceutical companies could list prices even higher in the future presumes that they are not launching products at the highest list price possible, currently.

But even if current launch price trends continue without any acceleration, high launch prices threaten to erase the savings generated by inflation rebates. **By 2026, when drugs are first eligible for negotiation, the average self-administered cancer drug launch price will be nearly $325,000 per year,** if current trends identified by our office persist. When the subset of CDER-regulated, physician-administered drugs examined in this report are also included in the analysis, the pricing figures are staggering. **This class of cancer drugs and therapeutic biologics would launch at an average annual price of $525,000 in 2026.**[67]

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[64] Kaiser Family Foundation, "Simulating the Impact of the Drug Price Negotiation Proposal in the Build Back Better Act" (Sept. 22, 2022) (online at https://www.kff.org/medicare/issue-brief/simulating-the-impact-of-the-drug-price-negotiation-proposal-in-the-build-back-better-act/).
[65] Committee for a Responsible Federal Budget, "What's in the Inflation Reduction Act?" (July 28, 2022) (online at https://www.crfb.org/blogs/whats-inflation-reduction-act).
[66] "Launch Prices: Tackling the Next Drug Pricing Challenge," *STAT News* (Sept. 8, 2022) (online at https://www.statnews.com/2022/09/08/launch-pricing-post-inflation-reduction-act-drug-pricing-challenge/).
[67] These figures were calculated by dividing the average launch price percent increase from 2017 to 2021 and dividing by the number of years of launch price increases (four years) to arrive at an average year-over-year launch price increase percentage. The year-over-year increase was multiplied by the 2021 average launch price to arrive at the 2022 average launch price, and was repeated for each year through 2026, when drugs will first be eligible for Medicare negotiation.

These drugs will be protected from negotiation for nine years, during which time manufacturers can apply price increases at the level of inflation. By the time these drugs are eligible for negotiation, not only will their prices be through the roof—but there will also likely be dozens of other cancer drugs that could generate savings equal to these newly launched products, if they were subject to negotiation. The Medicare program will only be able to choose 20 of them per year to lower prices. If drugmakers continue to rapidly increase launch prices for new products, they may be able to recoup revenue lost through negotiation and limit savings to patients and taxpayers.

Big Pharma asserts that any attempt to rein in drug prices will come at the expense of innovation. But Congressional investigations have found that blockbuster drugs—including cancer drugs—recoup the costs of research and development many times over.[68] Analyses of internal data reveal that pharmaceutical manufacturers invest more in financial maneuvers to enrich shareholders than in researching new cures. A report by the House Oversight Committee found that 14 of the largest drug companies spent more on stock buybacks, dividends, and executive compensation than they spent on research and development.[69] As one leading patient advocate and cancer patient put it, "The idea that taking a small bite out of pharma revenue is going to stop them from creating new drugs is bullshit."[70]

Addressing launch prices of new drugs will reduce pressure on the Medicare system to select eligible drugs for negotiation that would produce the most benefit. Pharmaceutical companies are already maneuvering to manipulate the negotiation eligibility criteria in the Inflation Reduction Act to prevent Medicare from negotiating fair prices for their drugs. For example, Revlimid, the second-costliest drug to the Medicare program, has been on the market since 2005.[71] Through a combination of market exclusivities, patent applications, and lawsuits against potential competitors, the manufacturers of Revlimid successfully prevented a generic equivalent from entering the market for years.[72]

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[68] House Committee on Oversight and Reform, *Drug Pricing Investigation: Majority Staff Report* (Dec. 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf).

[69] House Committee on Oversight and Reform, *Drug Pricing Investigation: Industry Spending on Buybacks, Dividends, and Executive Compensation* (July 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf).

[70] "Big Pharma Went All In to Kill Drug Pricing Negotiations," *Kaiser Health News* (Aug. 12, 2022) (online at https://khn.org/news/article/big-pharma-oppose-drug-pricing-negotiations-history/).

[71] Food and Drug Administration, *Highlights and Prescribing Information: Revlimid Label* (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021880s057lbl.pdf) (accessed Sept. 12, 2022).

[72] "How A Drugmaker Gamed The System To Keep Generic Competition Away," *NPR* (May 17, 2018) (online at https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away); House Committee on Oversight and Reform, *Drug Pricing Investigation: Celgene and Bristol Myers Squibb—Revlimid* (Sept. 30, 2020) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Celgene%20BMS%20Staff%20Report%2009-30-2020.pdf).

But as policymakers debated exempting drugs with generic competition from negotiation eligibility, the calculus of drugmakers appears to have changed. By 2022, Bristol Myers Squibb—Revlimid's manufacturer—had settled lawsuits authorizing five generic manufacturers to license and sell limited quantities of generic competitors to Revlimid. According to reports, these manufacturers will not be able to sell unlimited quantities of their generic products in the U.S. until 2026—21 years after Revlimid initially received FDA approval, and the first year that drugs will be eligible for negotiation.[73]

Drugmakers continually find loopholes to manipulate the prescription drug market. A comprehensive Congressional review of drug pricing practices by large pharmaceutical companies found numerous anticompetitive tactics used by drugmakers.[74] These tactics include applying for hundreds of frivolous patents to insulate products from competition and compensating competitors to delay generic entry (called "pay-for-delay" schemes).[75] Policymakers must limit anticompetitive behavior by manufacturers to reduce wasteful spending on drugs. But if Big Pharma continues to rig the prescription drug market against consumers, addressing launch prices will protect patients and taxpayers and reduce costs to our health system.

Unless Congress expands negotiation authority or reins in launch prices, it is possible that any savings achieved through limited price negotiation would be threatened by excessive launch prices for new drugs.

VII. Conclusion and Recommendations

Launch prices for cancer medications pose a grave financial threat to people with cancer and their families, taxpayers, and our health system. New cancer medications are entering the market at higher and higher prices, and few policy solutions have been discussed to address this major driver of health costs. The upward trajectory of launch prices suggest that these costs have not reached their ceiling, and even higher prices may be on the horizon.

[73] "Bristol Myers Squibb's Revlimid Finally Faces Competition in the U.S. with Teva's Generic Launch," *FiercePharma* (Mar. 7, 2022) (online at https://www.fiercepharma.com/pharma/bristol-myers-squibbs-revlimid-finally-faces-competition-us-tevas-generic-launch).
[74] House Committee on Oversight and Reform, *Drug Pricing Investigation: Majority Staff Report* (Dec. 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf).
[75] *Id.*

Prescription cancer drugs have the potential to extend and save lives for patients diagnosed with cancer. **But when priced out of reach for patients, a medical innovation is not a miracle. A prescription cannot save a life if it goes unfilled.**

This report exposes how exorbitant launch prices harm taxpayers and patients. First, high list prices cause different harms for different patients. Uninsured patients are exposed to full list prices, making it nearly impossible for these individuals to afford cancer drugs and start therapies they need. Depending on how patients split costs with their insurers, some insured Americans may be responsible for high costs tied to a drug's list price. Patients who receive their medication through high-deductible health plans or who pay coinsurance—a percentage of the list price of a medication—are disproportionately harmed by high list prices. Even those who have more generous coverage or who never need these drugs pay costs associated with high list prices through their insurance premiums. Solutions to high launch prices must consider all of these individuals.

Second, maximizing the many benefits of the Inflation Reduction Act requires reining in soaring launch prices. Medicare negotiation and inflation rebates will keep prices affordable for many patients and will generate billions of dollars in savings. But these tools would reach even more patients and even better protect taxpayers if launch prices were brought under control. Recent changes in the law, including the $2,000 out-of-pocket spending cap and the Part D benefit redesign, will help patients get the medications they need. But other provisions governing Medicare mean certain high-cost medications—including cancer drugs—could continue to drain taxpayer dollars.

Third, addressing launch prices would prevent abuse of market exclusivities and could provide an effective defense against corporate anticompetitive behavior. Newly launched products are often insulated from competition through patents and exclusive licensing arrangements recognized by the federal government. Pharmaceutical companies have long abused market exclusivity arrangements to delay or thwart generic competition. Now, as manufacturers may seek opportunities to manipulate competition and avoid providing fair prices to Medicare patients through negotiation, addressing launch prices could keep drugs affordable even if Big Pharma tries to rig the market against patients. If the launch prices for new medications continue increasing, however, pharmaceutical companies may be able to abuse market exclusivities to extract even higher revenues from patients and taxpayers.

To best protect patients and to maximize the benefits of the IRA's drug pricing provisions, Congress could pursue a number of policy options to rein in launch prices.

First, the U.S. could follow the example of peer nations and negotiate fair prices for new drugs based on the drugs' benefits and unique qualities. Nations that require pharmaceutical companies to price new medications in line with evidence of patient benefit and clinical effectiveness have lower cancer drug launch prices.[76] For example, three European nations that use prescription drug review boards to establish reasonable prices for new pharmaceutical products—England, Germany, and Switzerland—had significantly lower cancer launch prices than the United States. Notably, cancer drugs in these nations also experienced lower overall drug price increases.[77]

Second, policymakers can link drug prices to data on clinical efficacy and patient benefit by regulating launch prices for drugs that come to market under the accelerated approval pathway. Cancer drugs often launch under the accelerated approval program, in which drugs are introduced based on initial data and confirmatory studies are completed after market introduction. From 1992 to 2020, FDA granted more than 250 accelerated approval applications, most of which were for oncology drugs.[78]

When pharmaceutical companies launch their products at astronomical prices before demonstrating clinical benefit, there is little incentive to quickly complete studies confirming clinical and patient benefit. According to a recent study, 40 percent of accelerated approval drugs have incomplete confirmatory trials.[79] Of these applications with incomplete confirmatory trials, one in three has exceeded its original planned completion date.[80] An increasing number of accelerated approval drugs are being withdrawn from the market for various reasons, including a lack of confirmatory evidence or a failure to conduct trials promptly. Half of all such withdrawals have occurred since January 2021.[81] Patients should not pay a premium when pharmaceutical companies fail to prove the clinical benefits of their drugs. Instead, policymakers should consider limiting launch prices or mandating rebates for drugs that have not completed confirmatory trials. This will help secure affordable prices, safeguard patient safety, and reward high-quality treatments.

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[76] Kerstin N. Vokinger, et al., "Analysis of Launch and Postapproval Cancer Drug Pricing, Clinical Benefit, and Policy Implications in the US and Europe," *JAMA Oncology,* 7 (9): e212026 (Sept. 2021) (online at https://jamanetwork.com/journals/jamaoncology/fullarticle/2781390).
[77] *Id.*
[78] Arnold Ventures, "Accelerated Approval: Improving FDA Evidence Standards for Drugs and Biologics Approved Under the Accelerated Approval Program" (Mar. 17, 2022) (online at https://craftmediabucket.s3.amazonaws.com/uploads/AV-AcceleratedApprovalIssueBrief-v4.pdf).
[79] Office of the Inspector General, Department of Health and Human Services, *Delays in Confirmatory Trials for Drug Applications Granted FDA's Accelerated Approval Raise Concerns* (Sept. 29, 2022) (online at https://oig.hhs.gov/oei/reports/OEI-01-21-00401.pdf).
[80] *Id.*
[81] *Id.*

Through the Inflation Reduction Act, Congress tackled some of the most pressing issues threatening the ability of patients with cancer to afford the drugs they need. Out-of-pocket spending caps will save many of these Part D patients tens of thousands of dollars per year. Medicare negotiation will empower the government to target high-cost drugs that drive spending. Some of the provisions could even benefit Americans outside the Medicare program, including Congresswoman Porter's inflation rebate proposal that could rein in price increases for all Americans.

While these policy solutions represent significant progress, more must be done. To prevent additional abuses, Congress should consider the following proposals:

- **Establish a national drug pricing review board to recommend drug prices based on clinical benefits:** Big Pharma has proven itself incapable of pricing drugs in ways that reflect the value of new medication and help patients afford drugs. In numerous other nations, independent bodies evaluate patented medications to prevent excessive pricing. Nations with drug pricing review boards more closely align a drug's price with its clinical benefit and reduce costs to patients and health systems. States throughout the country have experimented with bills to allow independent regulators to evaluate information on prescription drugs, determine reasonable prices, and require drug prices not to exceed the recommended amount. These provisions are proven to protect taxpayers from excessive prices and help patients afford the drugs they need.

- **Limit the launch prices for drugs that have not demonstrated benefits to patients:** The accelerated approval pathway allows lifesaving, innovative therapies to reach patients quickly. But when these products are launched at astronomical prices before their value is confirmed, patients and taxpayers are forced to pay a premium for a product that may not work. Patients should have access to any therapy with promise, but that does not mean Big Pharma gets to name its price without following through on its obligation to prove that its drugs are safe and effective. Placing additional conditions on the launch prices of drugs brought to market under the accelerated approval pathway would balance the needs of patients who require innovative drugs with the duty of lawmakers to protect taxpayer dollars.

- **Tie public investments in research to reasonable price guarantees:** Congress has continued to provide resources to scientists and researchers developing breakthrough therapies. These public investments will save and extend lives. President Biden has proposed significant public investments in cancer

research, including through the Advanced Research Projects Agency for Health and his Cancer Moonshot initiative. This continued public investment in cancer research must be accompanied by conditions that require drugmakers to offer drugs developed with public funds at a reasonable price.

- **Remove Big Pharma carveouts that allow drugmakers to evade fair pricing policies:** Eliminating high costs begins with allowing Medicare to more fully and fairly negotiate drug prices. Congress should close loopholes that may allow pharmaceutical companies to manipulate Medicare negotiation, including pay-for-delay generic arrangements, patent abuse, and other anti-competitive tactics.

- **Require pharmaceutical companies to publicly disclose the list prices for products, including newly approved products:** Currently, wholesale acquisition cost (WAC) data—which indicates the retail price for prescription medications—are not publicly accessible. Analyses such as those included in this report must rely on secondarily reported data or require access to private databases. Policymakers need access to WAC data, including for newly launched products, to hold the pharmaceutical industry accountable for unfair pricing practices.

Appendix A

Methods and Analysis for Figure 1: Launch Prices for Self-Administered Cancer Drugs, 2017 and 2021

Figure 1 includes all novel drug approvals granted by the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) for 2017[82] and 2021 for self-administered cancer medications.[83] All therapies with a primary cancer indication are included in the table below. The analysis in Figure 1 excluded several CDER-approved drugs that are administered via infusion, or that may be used as part of a cancer therapy regiment, including one used to identify cancers or one used to alleviate symptoms associated with chemotherapy. The data included in this report derive from launch price data was publicly accessible or reported. The lack of a centralized, public database with key launch price data highlights the need for manufacturers to publicly disclose the list prices for their pharmaceutical products.

The chart below shows the name of the drug, the drug's FDA approved label, and the available pricing data that contributed to calculations contained in this report.

2021			
Name	**Cancer type**	**Dosing Data for Annual Price**	**Launch Price**
Besremi[84]	Blood Cancer	$6,988 per syringe[85]	$182,000[86]
Scemblix[87]	Leukemia	$17,900 for one month's supply (60 doses) of 40mg, administered twice daily[88]	$214,800

[82] Food and Drug Administration, *Novel Drug Approvals for 2017* (online at https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2017) (accessed Oct. 2, 2022).
[83] Food and Drug Administration, *Novel Drug Approvals for 2021* (online at https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021) (accessed Oct. 2, 2022).
[84] Food and Drug Administration, *Highlights and Prescribing Information: Besremi Label* (Nov. 11, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761166s000lbl.pdf).
[85] Conduent Business Services on behalf of Missouri Department of Social Services, Rare Disease Advisory Council, *Besremi New Drug Fact Blast* (2022) (online at https://dss.mo.gov/mhd/cs/advisory/rdac/pdf/besremi-blast.pdf).
[86] *Id.*
[87] Food and Drug Administration, *Highlights and Prescribing Information: Secmblix Label* (Oct. 29, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215358s000Orig1lbl.pdf).
[88] State of Vermont, Office of the Attorney General, *Notice of Introduction of High Cost Prescription Drug: Scemblix)* (Nov. 23, 2021) (online at https://ago.vermont.gov/wp-content/uploads/2022/03/VT-Report-of-Introduction-of-New-High-Cost-Prescription-Drugs-SCEMBLIX.pdf); Prime Therapeutics, *Specialty Pipeline Update* (November 2021) (online at https://www.primetherapeutics.com/wp-content/uploads/2021/11/NOV-21-Specialty_Pipeline-Update.pdf).

Tivdak[89]	Cervical Cancer	Excluded from Figure 1 analysis. Administered via infusion.	n/a
Exkivity[90]	Lung Cancer	$25,000 per month[91]	$299,995
Rylaze[92]	Leukemia and Lymphoma	Excluded from Figure 1 analysis. No publicly available pricing data.	n/a
Truseltiq[93]	Cholangiocarcinoma (Bile Duct Cancer)	$21,500 per month[94]	$258,000
Lumakras[95]	Lung Cancer	$17,900 per month[96]	$214,800
Pylarify[97]	Prostate Cancer (Diagnosis)	Excluded from analysis.	n/a
Rybrevant[98]	Lung Cancer	Excluded from Figure 1 analysis. Administered via infusion.	n/a

[89] Food and Drug Administration, *Highlights and Prescribing Information: Tivdak Label* (Sept. 20, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761208Orig1s000lbledt.pdf).
[90] Food and Drug Administration, *Highlights and Prescribing Information: Exkivity Label* (Sept. 15, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215310s000lbl.pdf).
[91] State of Vermont, Office of the Attorney General, *Notice of Introduction of High Cost Prescription Drug: Exkivity* (Oct. 20, 2021) (online at https://ago.vermont.gov/wp-content/uploads/2022/03/OBU-VT-New-Drug-Report-Exkivity-20211020.pdf).
[92] Food and Drug Administration, *Highlights and Prescribing Information: Rylaze Label* (June 30, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761179s000lbledt.pdf).
[93] Food and Drug Administration, *Highlights and Prescribing Information: Truseltiq Label* (May 28, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214622s000lbl.pdf).
[94] State of New Hampshire Insurance Department, *High Cost Prescription Drug Summary* (online at https://www.nh.gov/insurance/documents/highcost-rxsummary.xlsx) (access Oct. 2, 2022); Oklahoma Health Care Authority Drug Utilization Review Board, *Packet Contents for DUR Board Meeting – June 8, 2022* (June 8, 2022) (online at https://oklahoma.gov/content/dam/ok/en/okhca/docs/about/boards-and-committees/dur/2022/june/DUR%20Packet%2006082022.pdf); Global Health Reach, "Truseltiq Approved to Treat Aggressive Bile Duct Cancer" (June 1, 2021) (online at https://www.globalreachhealth.com/truseltiq-approved-to-treat-aggressive-bile-duct-cancer/).
[95] Food and Drug Administration, *Highlights and Prescribing Information: Lumakras Label* (May 28, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214665s000lbl.pdf).
[96] "In First, FDA Approves KRAS-blocking Cancer Drug from Amgen," *BioPharmaDive* (May 28, 2021) (online at https://www.biopharmadive.com/news/amgen-lumakras-fda-approval-first-kras-lung-cancer/600996/).
[97] Food and Drug Administration, *Highlights and Prescribing Information: Pylarify Label* (May 21, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214793s000lbl.pdf).
[98] Food and Drug Administration, *Highlights and Prescribing Information: Rybervant Label* (May 21, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761210s000lbl.pdf).

Zynlonta[99]	Lymphoma	Excluded from Figure 1 analysis. Administered via infusion.	n/a
Jemperli[100]	Endometrial Cancer	Excluded from Figure 1 analysis. Administered via infusion.	n/a
Fotivda[101]	Renal Cell Carcinoma	$24,150 per month[102]	$289,900
Papaxto[103]	Multiple Myeloma	Excluded from Figure 1 analysis. Administered via infusion.	n/a
Cosela[104]	Anti-immunosuppressant for Lung Cancer	Excluded from analysis.	n/a
Ukoniq[105]	Lymphoma	$15,900 per 30 days[106]	$190,800
Tepmetko[107]	Lung Cancer	$20,898.60 per 30 days[108]	$250,775

[99] Food and Drug Administration, *Highlights and Prescribing Information: Zynlonta Label* (Apr. 23, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761196s000lbl.pdf).
[100] Food and Drug Administration, *Highlights and Prescribing Information: Jemperli Label* (Apr. 22, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761174s000lbl.pdf).
[101] Food and Drug Administration, *Highlights and Prescribing Information: Fotivda Label* (Mar. 10, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212904s000lbl.pdf).
[102] "Aveo's Tivozanib, Now Approved as Fotivda, Will Hit the Market After Years of Setbacks," *FiercePharma* (Mar. 11, 2021) (online at https://www.fiercepharma.com/pharma/aveo-s-tivozanib-now-approved-as-fotivda-will-hit-market-after-years-setbacks).
[103] Food and Drug Administration, *Highlights and Prescribing Information: Pepaxto Label* (Feb. 26, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214383s000lbl.pdf).
[104] Food and Drug Administration, *Highlights and Prescribing Information: Cosela Label* (Feb. 12, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214200s000lbl.pdf).
[105] Food and Drug Administration, *Highlights and Prescribing Information: Ukoniq Label* (Feb. 5, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213176s000lbl.pdf).
[106] "Watch Out, Gilead: TG Therapeutics Wins FDA Nod for Potentially Safer Zydelig Rival," *FiercePharma* (Feb. 8, 2021) (online at https://www.fiercepharma.com/marketing/watch-out-gilead-tg-therapeutics-has-won-fda-nod-for-a-potentially-safer-pi3k-drug-than).
[107] Food and Drug Administration, *Highlights and Prescribing Information: Tepmetko Label* (Feb. 3, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214096s000lbl.pdf).
[108] "Merck KGaA Matches Novartis with FDA Green Light for Targeted Lung Cancer Drug Tepmetko," *FiercePharma* (Feb. 4, 2021) (online at https://www.fiercepharma.com/pharma/merck-kgaa-matches-novartis-fda-green-light-for-targeted-lung-cancer-drug-tepmetko).

The launch prices for newly approved cancer drugs and therapeutic biologics from 2017 are listed below in 2017 USD. The data in Figure 1 are adjusted to 2021 USD using the January 2017 and January 2021 values on the Department of Labor's Consumer Price Index calculator.[109]

2017			
Name	**Cancer type**	**Dosing Data for Annual Price**	**Launch Price (2017 US $)**
Calquence[110]	Lymphoma	$14,260 per month[111]	$171,120
Verzenio[112]	Breast Cancer	$10,948 per month[113]	$131,375
Aliqopa[114]	Lymphoma	Excluded from Figure 1 analysis. Administered via infusion.	n/a
Besponsa[115]	Leukemia	Excluded from Figure 1 analysis. Administered via infusion.	n/a
Idhifa[116]	Leukemia	$24,872 per month[117]	$298,465

[109] Bureau of Labor Statistics, Department of Labor, *CPI Inflation Calculator* (online at https://www.bls.gov/data/inflation_calculator.htm) (accessed Sept. 9, 2022).
[110] Food and Drug Administration, *Highlights and Prescribing Information: Calquence Label* (Oct. 31, 2017) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/210259s000lbl.pdf).
[111] "FDA Approves New Treatment for Lymphoma," *SFGate* (Oct. 31, 2017) (online at https://www.sfgate.com/business/article/FDA-approves-new-treatment-for-lymphoma-12321439.php).
[112] Food and Drug Administration, *Highlights and Prescribing Information: Verzenio Label* (Sept. 28, 2017) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208716Orig1s000lbl.pdf).
[113] "Lilly Steps Up to Rival Pfizer, Novartis with Verzenio Breast Cancer Approval," *FiercePharma* (Sept. 28, 2017) (online at https://www.fiercepharma.com/pharma/lilly-joins-pfizer-novartis-cdk-4-6-fray-verzenio-breast-cancer-approval).
[114] Food and Drug Administration, *Highlights and Prescribing Information: Aliqopa Label* (Sept. 14, 2017) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209936s000lbl.pdf).
[115] Food and Drug Administration, *Highlights and Prescribing Information: Besponsa Label* (Aug. 17, 2017) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761040s000lbl.pdf).
[116] Food and Drug Administration, *Highlights and Prescribing Information: Idhifa Label* (Aug. 1,, 2017) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209606s000lbl.pdf).
[117] "BRIEF-Celgene Says Monthly Wholesale Acquisition Cost of AML Treatment Idhifa is $24,872," *Reuters* (Aug. 1, 2017) (online at https://www.reuters.com/article/brief-celgene-says-monthly-wholesale-acq/brief-celgene-says-monthly-wholesale-acquisition-cost-of-aml-treatment-idhifa-is-24872-idUSFWN1KN0SD).

Rydapt[118]	Leukemia	$14,990 per 28 days[119]	$194,870
Alunbrig[120]	Lung Cancer	$14,250 per month[121]	$171,000
Zejula[122]	Ovarian Cancer	$118,000 per year[123]	$118,000
Kisqali[124]	Breast Cancer	According to public reports, "A 28-day supply of the 600-mg dose will cost $10,950, while the same supply of the 400-mg dose will go for $8,760 and the 200-mg dose will run at $4,380."[125] Kisqali's FDA label recommends a 600-mg dose taken 21 consecutive days, with 7 days off.[126] This report calculates the annual dosage based on the highest possible dosing.	$142,350

[118] Food and Drug Administration, *Highlights and Prescribing Information: Rydapt Label* (Apr. 28, 2017) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/207997s000lbl.pdf).
[119] "U.S. FDA approves Novartis' leukemia treatment," *Reuters* (Apr. 28, 2017) (online at https://www.reuters.com/article/us-novartis-fda/u-s-fda-approves-novartis-leukemia-treatment-idUSKBN17U246).
[120] Food and Drug Administration, *Highlights and Prescribing Information: Alunbrig Label* (Apr. 28, 2017) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208772lbl.pdf).
[121] "FDA Gives Thumbs Up to Takeda's Lung Cancer Drug," *BioPharmaDive* (May 1, 2017) (online at https://www.biopharmadive.com/news/fda-gives-thumbs-up-to-takedas-lung-cancer-drug/441653/).
[122] Food and Drug Administration, *Highlights and Prescribing Information: Zejula Label* (Mar. 27, 2017) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208447lbl.pdf).
[123] "Tesaro and Its New Med Zejula Are on the Block, but Bidders Aren't Rushing In: WSJ," *FiercePharma* (Jun. 1, 2017) (online at https://www.fiercepharma.com/pharma/tesaro-s-block-but-so-far-bidders-aren-t-rushing-wsj).
[124] Food and Drug Administration, *Highlights and Prescribing Information: Kisqali Label* (Mar. 13, 2017) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209092s000lbl.pdf).
[125] "Novartis Rolls Out Flex Pricing Scheme for Newly Approved Ibrance Rival Kisqali," *FiercePharma* (Mar. 13, 2017) (online at https://www.fiercepharma.com/pharma/novartis-rolls-out-flex-pricing-scheme-for-newly-approved-ibrance-rival-kisqali).
[126] Food and Drug Administration, *Highlights and Prescribing Information: Kisqali Label* (Mar. 13, 2017) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209092s000lbl.pdf).

Appendix B

Methods and Analysis for CDER Regulated Cancer Drug Launch Prices

In addition to all data on self-administered drugs listed in Appendix A, the following information was used to calculate the annualized launch prices for drugs with approvals granted by the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) for 2017 and 2021.

The analysis excluded the lymphoblastic leukemia and lymphoblastic lymphoma therapy Rylaze, for which no launch price data was publicly accessible or reported. The unavailability of key launch price data highlights the need for manufacturers to publicly disclose the list prices for their products.

2021			
Name	**Cancer type**	**Dosing Data for Annual Price**	**Launch Price**
Tivdak[127]	Cervical Cancer	$5,885 per single dose vial[128]	$529,650[129]
Rylaze[130]	Leukemia and Lymphoma	Excluded from analysis. No publicly available pricing data.	n/a
Rybrevant[131]	Lung Cancer	According to research materials prepared for the Oklahoma Drug Pricing Review Board: "The WAC is $449.67 per mL resulting in a cost per dose of $12,590.76 for an 80kg adult based on the recommended dosing. The cost of initial dosing for an 80kg adult would be $50,363.04 for the first 4 weeks and $25,181.52 per month thereafter."[132]	$327,360

[127] Food and Drug Administration, *Highlights and Prescribing Information: Tivdak Label* (Sept. 20, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761208Orig1s000lbledt.pdf).
[128] "Seagen, Genmab win speedy FDA approval for cervical cancer drug," *BioPharmaDive* (Sept. 21, 2021) (online at https://www.biopharmadive.com/news/seagen-genmab-fda-approval-cervical-cancer-tivdak/606926/); Oklahoma Health Care Authority Drug Utilization Review Board, *Packet Contents for DUR Board Meeting – June 8, 2022* (June 8, 2022) (online at https://oklahoma.gov/content/dam/ok/en/okhca/docs/about/boards-and-committees/dur/2022/june/DUR%20Packet%2006082022.pdf).
[129] Oklahoma Health Care Authority Drug Utilization Review Board, *Packet Contents for DUR Board Meeting – June 8, 2022* (June 8, 2022) (online at https://oklahoma.gov/content/dam/ok/en/okhca/docs/about/boards-and-committees/dur/2022/june/DUR%20Packet%2006082022.pdf).
[130] Food and Drug Administration, *Highlights and Prescribing Information: Rylaze Label* (June 30, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761179s000lbledt.pdf).
[131] Food and Drug Administration, *Highlights and Prescribing Information: Rybervant Label* (May 21, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761210s000lbl.pdf).
[132] Oklahoma Health Care Authority Drug Utilization Review Board, *Packet Contents for DUR Board Meeting –May 11, 2022* (May 11, 2022) (online at https://oklahoma.gov/content/dam/ok/en/okhca/docs/about/boards-and-committees/dur/2022/may/05112022%20DUR%20Packet.pdf).

Zynlonta[133]	Lymphoma	Zynlonta is administered via an initial dose of 0.15mg/kg via intravenous (IV) infusion every 3 weeks for 2 cycles, followed by 0.075mg/kg infusions every 3 weeks for subsequent cycles. According to research materials prepared for the Oklahoma Drug Pricing Review Board: "The Wholesale Acquisition Cost (WAC) is $23,770.25 per vial, resulting in a cost for the initial doses of $47,540.50 and $23,770.25 for subsequent doses for an adult weighing 75kg."[134] For an 80kg individual (to keep per kg calculations consistent for all drugs), the cost of the initial doses would be $50,709.86 and subsequent doses would be $25,354.93.	$490,195
Jemperli[135]	Endometrial Cancer	$15,000 per month[136]	$186,000[137]
Papaxto[138]	Multiple Myeloma	$9,500 per single dose vial, resulting in a cost per 28 days of $19,000 at the recommended dose.[139]	$247,000

The launch prices for newly approved cancer drugs and therapeutic biologics from 2017 are listed below in 2017 USD.

[133] Food and Drug Administration, *Highlights and Prescribing Information: Zynlonta Label* (Apr. 23, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761196s000lbl.pdf).
[134] Oklahoma Health Care Authority Drug Utilization Review Board, *Packet Contents for DUR Board Meeting –May 11, 2022* (May 11, 2022) (online at https://oklahoma.gov/content/dam/ok/en/okhca/docs/about/boards-and-committees/dur/2022/may/05112022%20DUR%20Packet.pdf).
[135] Food and Drug Administration, *Highlights and Prescribing Information: Jemperli Label* (Apr. 22, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761174s000lbl.pdf).
[136] "Latecomer GlaxoSmithKline Ushers in 7th PD-1/L1 with FDA Nod for Jemperli, Treading on Keytruda's Ground," *FiercePharma* (Apr. 23, 2021) (online at https://www.fiercepharma.com/pharma/latecomer-glaxosmithkline-ushers-7th-pd-1-l1-fda-nod-for-jemperli-treading-keytruda-ground); Oklahoma Health Care Authority Drug Utilization Review Board, *Packet Contents for DUR Board Meeting –December 8, 2021* (Dec. 8, 2021) (online at https://oklahoma.gov/content/dam/ok/en/okhca/docs/about/boards-and-committees/dur/2021/december/DUR%20Packet%2012082021.pdf).
[137] Oklahoma Health Care Authority Drug Utilization Review Board, *Packet Contents for DUR Board Meeting –December 8, 2021* (Dec. 8, 2021) (online at https://oklahoma.gov/content/dam/ok/en/okhca/docs/about/boards-and-committees/dur/2021/december/DUR%20Packet%2012082021.pdf).
[138] Food and Drug Administration, *Highlights and Prescribing Information: Pepaxto Label* (Feb. 26, 2021) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214383s000lbl.pdf).
[139] Oklahoma Health Care Authority Drug Utilization Review Board, *Packet Contents for DUR Board Meeting –December 8, 2021* (Dec. 8, 2021) (online at https://oklahoma.gov/content/dam/ok/en/okhca/docs/about/boards-and-committees/dur/2021/december/DUR%20Packet%2012082021.pdf).

2017			
Name	**Cancer type**	**Dosing Data for Annual Price**	**Launch Price**
Aliqopa[140]	Lymphoma	$12,600 per 28 days in December 2018, one year after launch.[141] After accounting for an 8.9% price increase applied in 2018,[142] the calculated 2017 launch price equals $11,570 per 28 days.	$150,410
Besponsa[143]	Leukemia	According to public reporting: "In the U.S., Pfizer has said that based on the typical duration of treatment, the total cost of the drug will be $168,300...."[144] While the FDA label notes that the recommended dosing is two cycles,[145] there is no evidence that the recommended dose aligns with Pfizer's reported "typical" duration.	$168,300

To arrive at the final calculations, our office combined the data from Appendix A with the data in Appendix B. The data used in the calculation contained in the report are adjusted to 2021 USD using the January 2017 and January 2021 values on the Department of Labor's Consumer Price Index calculator.[146] The chart below shows our office's analysis, with physician-administered medications colored yellow:

[140] Food and Drug Administration, *Highlights and Prescribing Information: Aliqopa Label* (Sept. 14, 2017) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209936s000lbl.pdf).
[141] Sreevalsa Appukkuttan, et al., "A Budget Impact Analysis of the Introduction of Copanlisib for Treatment of Relapsed Follicular Lymphoma in the United States," *Journal of Managed Care and Specialty Pharmacy* 25 (4), 437-446 (Apr. 2019) (online at https://pubmed.ncbi.nlm.nih.gov/30608008/).
[142] 46Brooklyn, *Brand Drug List Price Change Box Score* (online at https://www.46brooklyn.com/branddrug-boxscore) (accessed Aug. 16, 2022).
[143] Food and Drug Administration, *Highlights and Prescribing Information: Besponsa Label* (Aug. 17, 2017) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761040s000lbl.pdf).
[144] "Pfizer Lashes Out at 'Frustrating' NICE Decision on ALL Drug Besponsa," *FiercePharma* (online at https://www.fiercepharma.com/pharma/pfizer-lashes-out-at-frustrating-nice-decision-all-drug-besponsa).
[145] Food and Drug Administration, *Highlights and Prescribing Information: Besponsa Label* (Aug. 17, 2017) (online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761040s000lbl.pdf).
[146] Bureau of Labor Statistics, Department of Labor, *CPI Inflation Calculator* (online at https://www.bls.gov/data/inflation_calculator.htm) (accessed Sept. 9, 2022).

2017					2021			
Name	Date	Cancer type	Launch Price (2017 USD)	Launch Price (2021 USD)	Name	Date	Cancer type	Launch Price
Calquence	10/31/2017	Lymphoma	171,120	184,327	Besremi	11/12/2021	Blood Cancer	182,000
Verzenio	9/28/2017	Breast Cancer	131,375	141,515	Scemblix	10/29/2021	Leukemia	214,800
Aliqopa	9/14/2017	Lymphoma	150,410	162,019	Tivdak	9/20/2021	Cervical Cancer	529,650
Besponsa*	8/17/2017	Leukemia	168,300	181,290	Exkivity	9/15/2021	Lung Cancer	299,995
Idhifa	8/1/2017	Leukemia	298,465	321,501	Truseltiq	5/28/2021	Cholangiocarcinoma	258,000
Rydapt	4/28/2017	Leukemia	194,870	209,911	Lumakras	5/28/2021	Lung Cancer	221,240
Alunbrig	4/28/2017	Lung Cancer	171,000	184,198	Rybrevant	5/21/2021	Lung Cancer	327,360
Zejula	3/27/2017	Ovarian Cancer	118,000	127,108	Zynlonta	4/23/2021	Lymphoma	490,195
Kisqali	3/13/2017	Breast Cancer	131,400	141,542	Jemperli	4/22/2021	Endometrial Cancer	186,000
					Fotivda	3/10/2021	Renal Cell Carcinoma	289,900
					Pepaxto	2/26/2021	Multiple Myeloma	247,000
					Ukoniq	2/5/2021	Lymphoma	190,800
					Tepmetko	2/3/2021	Lung Cancer	250,775
		AVERAGE	171,766	185,023			AVERAGE	283,175
		MEDIAN	172,199	185,489			MEDIAN	250,775

* While all other drugs are calculated using annualized costs, the only publicly reported figure for Besponsa represented the cost ($168,300 in 2017 USD) for a "typical course of treatment." Because the FDA label for Besponsa states that the drug can be taken for two to six cycles, there is no consistent way to annualize the costs of treatment. Therefore, the reported "typical" cost of Besponsa is included. Staff notes that both the inclusion and exclusion of Besponsa at this price only changes the average price by less than one percent and does not change the median price.