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Companies That Manufacture The 10 Most Expensive Drugs Covered By Medicare Spent $60 Million Since Q1 2023 While Lobbying Against Efforts To Lower Drug Costs At The Expense Of Americans Living With Disabilities

Summary: On April 02, 2024, the Centers for Medicare and Medicaid (CMS) rejected pharmaceutical companies' price offers, "kicking off talks expected to stretch through the summer." CMS Administrator Chiquita Brooks-LaSure said, “CMS is proud to be negotiating in good faith with drug manufacturers to lower the prices of some of the most expensive drugs for people with Medicare."

The Kaiser Family Foundation (KFF)—an independent health policy research organization—estimated that 7.8 million beneficiaries on Medicare were living with a disability in 2021. The U.S. Census Bureau's 2022 data also shows that over 44.1 million Americans were living with at least one disability as of 2022. Leading causes of disability include neurological disease as well as rheumatoid arthritis, with arthritis generally quickly becoming a leading cause of work-related disability according to the National Institutes of Health (NIH).

In 2021, Eliquis, Revlimid, Xarelto, Trulicity, Januvia, Jardiance, Imbruvica, Humira, Lantus, and Ozempic accounted for the majority of spending by Medicare, with just these 10 drugs costing Medicare over $46.8 billion in 2021 alone. All of these drugs are used to help patients with disabilities, including rheumatoid arthritis, diabetes, cancer, and other ailments impacting an individual's quality of life. Several of these drugs, including Eliquis, Jardiance, Xarelto, Januvia, and Imbruvica were also among the first 10 drugs set to have their prices negotiated with Medicare under the Inflation Reduction Act.

A major cause of sky-rocketing drugs is drug companies' abuse of the U.S. patent system, where seven out of the ten most expensive drugs held on average 74 patents for a single medication. One egregious example of the drug Eylea—used to treat an eye condition known as macular degeneration that affects older adults—had 90 patents on the medication, allowing the manufacturer Regeneron to charge a staggering $1,800 for a *single dose.*

An Accountable.US review of drug manufacturers that make these life-saving drugs used by the disabled community shows they have collectively spent over $60 million since Q1 2023 while lobbying against the Inflation Reduction Act, legislation to lower drug prices, and reforms to the U.S. patent system. Among these are:

Bristol Myers Squibb (BMS) is the maker of blood thinner Eliquis and cancer treatment Revlimid:

- Eliquis is used by over 3.5 million Medicare beneficiaries as of 2022 and has had its price skyrocket since its introduction into the marketplace, with BMS hiking the cost of this drug by 43% from 2017 to 2022. The blood thinner has key patents set to expire from 2027 to 2029, and has used its monopoly to sue competitors in efforts to block biosimilars from cutting into its revenue stream. In 2022 alone, Eliquis made up 25% of Bristol Myers' sales, and is estimated to make the company $478 million in future revenue by 2032.

- Revlimid is prescribed to at least 45,601 Medicare beneficiaries as of 2021. The drug was the center of a lawsuit brought by Mayo Clinic and LifePoint Health in October 2023 with the two alleging that BMS and its subsidiary Celgene conspired with other manufacturers to significantly delay the production of biosimilars, claiming that BMS even coerced companies in a "pay for delay" scheme to pushback generics from entering the market.

- In June 2023, BMS sued the Biden Administration over the Inflation Reduction Act's Medicare drug negotiation provision and is a board member of the Pharmaceutical Research and Manufacturers of America (PhRMA), which also sued the Biden Administration in June 2023. Former BMS CEO Giovanni Caforio also wrote an August 2023 op-ed blasting the law, claiming it would "sen[d] a signal that industry should walk away from medicines for the elderly," alleging it does not "involve any negotiation in any sense of the word."

- Meanwhile, Bristol Myers has **spent over $9.4 million since Q1 2023** while lobbying on issues related to "implementation of the Inflation Reduction Act," drug rebates, drug pricing, and opposing "H.R. 4895 The Lowering Drug Costs For American Families Act."

Johnson & Johnson is the maker of blood thinner Xarelto, which is prescribed to over 1.3 million Medicare enrollees as of 2022. Medicare spent a staggering $5.8 billion for Xarelto in 2022 alone, with the drug selected to be one of the first ten drugs to have prices negotiated with Medicare.

- Xarelto patent holders Janssen Pharmaceuticals—a subsidiary of Johnson & Johnson—and Bayer have filed lawsuits in efforts to block generics from entering the marketplace. However, an April 2024 ruling by a British court found that Bayer's patent of Xarelto was "invalid," a ruling that "pave[d] the way for other drug makers to launch generic versions." A key patent for Xarelto is set to expire in 2026, according to Proclinical.

- Johnson & Johnson is also represented on the board of PhRMA, which filed a June 2023 lawsuit challenging the Biden Administration's efforts to rein in prescription drug prices. Johnson & Johnson followed with its own suit in July 2023, becoming the third major drug manufacturer to file a suit challenging the law.

- Meanwhile, Johnson & Johnson **spent over $9.5 million since Q1 2023** while lobbying on issues related to Medicaid rebates, implementation of the Inflation Reduction Act and issues related to biosimilars.

Eli Lilly and Company is the maker of Trulicity and Jardiance, both of which are used to treat diabetes:

- Medicare spent a staggering $6.2 billion for Trulicity in 2022 alone, and a key patent for Trulicity is not set to expire until 2027, according to Proclinical.

- Jardiance is prescribed to over 1.3 million Medicare beneficiaries as of 2022, with the program spending $5.9 billion for the medication in 2022 alone. The government also selected Jardiance as one of the first 10 medications to be negotiated with Medicare.

- In August 2023, nine states warned against a proposed settlement with Eli Lilly over an insulin price-fixing class action lawsuit arguing it would shield the company from future suits, before Eli Lilly, Novo Nordisk and Sanofi walked back on the agreement.

- Meanwhile, Eli Lilly has spent **over $9.6 million since Q1 2023** while lobbying against implementation of the Inflation Reduction Act, S. 954 "The Affordable Insulin Now Act," and issues related to intellectual property and patent protections.

Merck is the maker of Januvia, which is used to treat diabetes. In 2022, 885,000 Medicare enrollees were prescribed the medication, for which Medicare spent $4.1 billion in 2022. Januvia was also selected as one of the first 10 medications set to have its price negotiated with Medicare.

- Merck won a battle over a patent that was set to expire on Januvia in early 2023 after a court sided with the manufacturer who claimed that competitors infringed on its patent. The drug maker subsequently boasted to investors that Merck expected to "maintain U.S. market exclusivity on Januvia until about May 2026." Since Januvia was launched in 2006, Merck has hiked the drug price by 275 percent, and currently charges patients in America 5.5 times more than those in Canada and over 20 times more than consumers in Germany.

- In June 2023, Merck filed a lawsuit challenging the Inflation Reduction Act's Medicare prescription drug price negotiation provision alleging the law violated the fifth amendment and that it would lead to the government "tak[ing] Merck's patented innovations by coercing the company to provide third parties with access." Merck is also a board member of PhRMA, which filed its own lawsuit shortly following Merck's initial lawsuit.

- Meanwhile, Merck has **spent over $12.1 million since Q1 2023** while lobbying against the Inflation Reduction Act, "H.R. 4895 The Lowering Drug Costs For American Families Act," "H.R. 3 The Elijah E. Cummings Lower Drug Costs Now Act," and other issues related to patent and trademark laws.

AbbVie is the maker of cancer treatment Imbruvica and rheumatoid arthritis drug Humira:

- Imbruvica was prescribed to 22,000 Medicare enrollees as of 2022 and is set to have its price negotiated with by Medicare after AbbVie charged the program $3.2 billion for the drug in 2022 alone. It's also one of the first 10 drugs to have its price negotiated with by Medicare.

- Humira was prescribed to about 42,000 Medicare patients in 2020. In March 2023, AbbVie was also ordered to pay back the government after it hiked the price of Humira well beyond the rate of inflation.

- In January 2023, AbbVie's monopoly on Humira ended after seven drugs were set to enter the marketplace, including a biosimilar manufactured by Amgen, after AbbVie successfully filed 165 patents on the drug, which earned it a **staggering $208 billion in global revenue** from 2002 to 2022.

- Since Q1 2023, AbbVie has **spent over $5.2 million while lobbying** against S. 142 "The Preserve Access to Affordable Generics and Biosimilars Act," issues related to intellectual property, the 340B rebate program, and Medicare Part D drug negotiations, among other issues.

Sanofi is the maker of insulin medication Lantus Solostar, and charged Medicare $2.9 billion for the drug in 2022 alone.

- In 2021, Sanofi was defeated in federal court after a patent board denied its efforts to "revive parts of patents relates to its Lantus SoloStar insulin pens," with Sanofi accusing competitor Mylan of attempting to make a generic version of the medication, which earned Sanofi over $3 billion in sales in 2020. In 2023, the Federal Trade Commission (FTC) supported an antitrust lawsuit brought by Mylan accusing Sanofi of operating a "multifaceted monopolization scheme" by abusing the patent system and submitting "invalid" and "uninfringed" patent applications to further delay biosimilars from entering the marketplace.

- Since Q1 2023, Sanofi **spent over $7.5 million while lobbying** on issues related to intellectual property, Medicare negotiations and the 340B drug rebates program, among other issues impacting prescription drugs pricing.

Novo Nordisk is the maker of insulin drug Ozempic, which was prescribed to 500,000 Medicare enrollees in

2021. In 2021, Novo Nordisk charged Medicare $2.6 billion for the drug.

- In October 2023, Novo Nordisk—which became Europe's highest valued company in September 2023—squashed a challenge by Mylan Pharmaceuticals in an attempt to begin manufacturing a generic version of Ozempic, despite a patent board agreeing to evaluate one of its patents which isn't set to expire until June 2033.

- Novo Nordisk—who sits on PhRMA's board of directors—filed its own lawsuit challenging the IRA's Medicare drug price negotiation provision in September 2023 joining other companies claiming it violated the First and Fifth Amendments calling it "price controls."

- Meanwhile, Novo Nordisk **spent over $6.4 million since Q1 2023** while lobbying on insulin pricing, patent protection and IRA implementation, among other issues.

Background

According To Kaiser Family Foundation (KFF), At Least 7.8 Million Americans On Medicare Reported A Disability In 2021, With Ailments Like Arthritis And Neurological Disability The Most Common Among The U.S. Population, With Over 53.2 Million Americans Reported Having Arthritis From 2019 To 2021.

Data In 2021 And 2023 Show That There Are About 7.4 To 7.8 Million Of Medicare Beneficiaries Living With A Disability.

According To The Kaiser Family Foundation (KFF), 7.8 Million Medicare Beneficiaries Were Disabled As Of 2021. [KFF, accessed 03/19/24]

Similar Statistics By The Centers For Medicare And Medicaid (CMS) Had Disabled Persons With Medicare At An Average Of 7.4 Million A Month In 2023. [Centers for Medicare & Medicaid Services, accessed 03/19/24]

According To The U.S. Census Bureau, The Most Common Disability In The U.S. Are Those Suffering From "Ambulatory Difficulty," Which Impacts An Individual's Ability To Walk Or Climb Stairs.

Label	Estimate
Total:	328,309,810
With a disability:	44,146,764
With a hearing difficulty	12,034,657
With a vision difficulty	8,181,582
With a cognitive difficulty	17,524,606
With an ambulatory difficulty	20,905,277
With a self-care difficulty	7,999,365
With an independent living difficulty	15,778,150
No disability	284,163,046

[U.S. Census Bureau, accessed 03/14/24]

- **According To The U.S. Census Bureau, "Ambulatory Difficulty" Is Defined As A Person "Having Serious Difficulty Walking Or Climbing Stairs (DPHY)."** [U.S. Census Bureau, accessed 03/14/24]

- **The U.S. Census Bureau Says, "Because Of A Physical, Mental, Or Emotional Problem, Having Difficulty Doing Errands Alone Such As Visiting A Doctor's Office Or Shopping (DOUT)," Is Considered "Independent Living Difficulty."** [U.S. Census Bureau, accessed 03/14/24]

According To The Centers For Disease Control And Prevention (CDC), A Leading Cause Of Work-Related Disability Is Arthritis, With 53.2 Million Adults Aged 18 Or Older Reporting Doctor-Diagnosed Arthritis From 2019 To 2021.

According To Data Collected By The Centers For Disease Control And Prevention (CDC), 53.2 Million, Or 21% Of Americans Aged 18 Or Older Have Doctor-Diagnosed Arthritis. "During 2019–2021, 21.2% of U.S. adults (53.2 million) reported diagnosed arthritis." [Centers for Disease Control and Prevention, 10/13/23]

- **The CDC Says That Arthritis Is A Leading Cause Of Work Disability Among U.S. Adults.** "Arthritis affects a person's overall function and mobility, which can result in activity and other limitations. It is a leading cause of work disability among US adults. Learn about the prevalence of arthritis-related limitations in the United States, and how CDC defines disability and limitations." [Centers for Disease Control and Prevention, accessed 04/15/24]

A March 2024 Study Conducted By The Lancet Neurology Found That Neurological Conditions Were The Global Leading Cause Of Illness And Disability In 2021, Including Stroke, Diabetes, Dementia And Others As The Top 10 Leading Causes.

March 2024: The World Health Organization (WHO) Cited A Study By The Lancet Neurology That Found Neurological Conditions Are Now The Leading Cause Of Illness And Disability Worldwide, With "Disability-Adjusted Life Years" Increasing By 18% Since 1990. "A major new study released by The Lancet Neurology shows that, in 2021, more than 3 billion people worldwide were living with a neurological condition. The World Health Organization (WHO) contributed to the analysis of the Global Burden of Disease, Injuries, and Risk Factor Study (GBD) 2021 data. Neurological conditions are now the leading cause of ill

health and disability worldwide. The overall amount of disability, illness and premature death (known as disability-adjusted life years, DALYs) caused by neurological conditions has increased by 18% since 1990." [World Health Organization, 03/14/24]

"The Top Ten Neurological Conditions Contributing To Loss Of Health In 2021 Were Stroke, Neonatal Encephalopathy (Brain Injury), Migraine, Dementia, Diabetic Neuropathy (Nerve Damage), Meningitis, Epilepsy, Neurological Complications From Preterm Birth, Autism Spectrum Disorder, And Nervous System Cancers." "The top ten neurological conditions contributing to loss of health in 2021 were stroke, neonatal encephalopathy (brain injury), migraine, dementia, diabetic neuropathy (nerve damage), meningitis, epilepsy, neurological complications from preterm birth, autism spectrum disorder, and nervous system cancers." [World Health Organization, 03/14/24]

A February 2024 Study By Bentley University Found The First Ten Medications Set To Be Negotiated With Medicare Cost Taxpayers Anywhere From $227 Million To $6.7 Billion—A Combined $11 Billion—With 7.7 Million Medicare Enrollees Being Prescribed These Life Saving Medications, As Americans Continue To Struggle To Afford Prescriptions, With An Estimated 18 Million Americans Forcing To Skip Dosages In 2021.

According To A February 2024 Study By Bentley University, The National Institutes Of Health Funded Anywhere From $227 Million To $6.5 Billion On The First 10 Prescription Drugs That Are Set To Be Negotiated With Medicare, Of Which 7.7 Million Enrollees Take, As Rising Costs Of Prescription Drugs Have Forced 18 Million Americans To Skip Dosages.

February 2024: A Study From The Center For Integration Of Science And Industry At Bentley University Found The First 10 Drugs Set To Be Negotiated By Medicare "Received Anywhere From $227 Million To $6.5 Billion In Funding" From The National Institutes Of Health, With 7.7 Million Medicare Enrollees Prescribed These Medications To Treat Conditions Such As Blood Clots, Diabetes, Autoimmune Diseases And Other Disabilities And Ailments. "According to the new study out of the Center for Integration of Science and Industry at Bentley University, which was published early March, the 10 selected prescription drugs received anywhere from $227 million to $6.5 billion in funding from the government's National Institutes of Health (NIH) for crucial, foundational research. [...] These drugs, which are covered by Medicare's prescription drug benefit plan, are taken by 7.7 million enrollees, most of them elderly, to treat conditions including blood clots, heart failure, diabetes, autoimmune conditions, and chronic kidney disease. In 2022, Medicare patients spent $3.4 billion out of pocket on these medications, a number that increased by 116 percent over a four-year span." [The Lever, 02/22/24]

- **American Taxpayers Spent An Estimated Total of $11.7 Billion On Research For The 10 Drugs, With Their Makers Reaping $70 Billion In Profits On Them In 2022 Alone.** "Now a bombshell new report reveals that Americans funded the development of all 10 drugs up for price negotiations, shelling out a total of $11.7 billion on their research. In 2022 alone, Big Pharma made $70 billion selling those same drugs — and now they want to keep their prices sky high." [The Lever, 02/22/24]

A 2021 Gallup Survey Found That Adults Nationwide Are Struggling To Afford The Rising Costs Of Prescription Drugs, With 18 Million Americans Saying They Are Forced To Skip Dosages. "The rising cost of prescription drugs is a critical issue in American health care. From 2008 to 2021, the launch prices of new drugs increased by 20 percent per year, forcing 18 million Americans to skip essential dosages, according to a 2021 Gallup survey of adults nationwide." [The Lever, 02/22/24]

Having To Skip Dosages Disproportionately Affects Households Earning $48,000 Or Less A Year And Black And Hispanic Communities.

The Prices Of Prescription Drugs Disproportionately Impacts Households In Lower-Income Brackets, With 18% Of Households Earning Less Than $48,000 A Year Saying They Or A House Member Were Forced To Skip A Dose To Save Money, With More Than Five Million Medicare Beneficiaries Struggling To Afford Drug Costs. "High prices are particularly harmful for lower-income households. Of survey respondents earning less than $48,000 per year, 18 percent reported they or someone in their home had skipped a dose to save money. More than five million Medicare beneficiaries struggle to afford their prescriptions, particularly those who do not receive a low-income subsidy that lowers out-of-pocket spending." [The Lever, 02/22/24]

Meanwhile, "Black And Latino Enrollees Report Affordability Problems At 1.5 To 2 Times The Rate Of Their White Counterparts." "Additionally, Black and Latino enrollees report affordability problems at 1.5 to 2 times the rate of their white counterparts." [The Lever, 02/22/24]

U.S. Census Data Also Shows That Disability-Related Health Conditions In 2021 Predominantly Affected Black And Other Minorities The Highest. "Among adults ages 40 and older, non-Hispanic Asians reported the lowest rates of disability-related health conditions in 2021 while those in the non-Hispanic Black and Other race categories had the highest rates." [U.S. Census Bureau, 07/12/23]

31.8% Of Black Adults And 42.9% Of Multiple-Raced Americans Reported A Disability In 2021. "Black (non-Hispanic) adults (31.8%) and those reporting Other or multiple-race non-Hispanic identity (42.9%) were among those with higher rates." [U.S. Census Bureau, 07/12/23]

As Of February 2024, Seven Of The Top 10 Drugs Hold On Average 74 Patents, Which Has Contributed To The Skyrocketing Price Of Prescription Drugs.

As Of February 2024, Seven Of The Top 10 Drugs Hold On Average 74 Patents, Which Has Contributed To The Skyrocketing Price Of Prescription Drugs.

According To TIME, 7 Of The 10 Top Selling Drugs Are Set To Have Patents Expire On Their Drugs Within The Next Decade—However, Failing To Pay Attention To Patent Abuse Could "Extend Their Patent Protection, Delay Competition, And Keep The Cost Of Life-Saving Medicines Sky High." "To fully grasp drugmakers' vehement pushback on any attempts to reduce drug prices, it's important to pull back the curtain on the industry's ongoing anti-competitive practices to see what else is really at stake. Patent monopolies on 7 out of 10 of America's top selling drugs should expire this decade. This means drugmakers stand to lose billions if—and when—lower-priced generic alternatives are allowed on the market. But unless America wises up to the industry's under-the-table patent games, drugmakers will continue to have free rein to extend their patent protection, delay competition, and keep the cost of life-saving medicines sky high." [TIME, 02/24/23]

A February 2024 Report Found That The Top 10 Selling Drugs Have An Average Of 140 Patents Filed, With 74 Patents Granted, Even After The Drugs Were Approved By The FDA. "A recent national report reveals that, on average, there are 140 patents filed and 74 patents granted on each of America's 10 top-selling drugs. Sixty-six percent of these patent applications were filed after FDA approval – many for very minor product modifications." [TIME, 02/24/23]

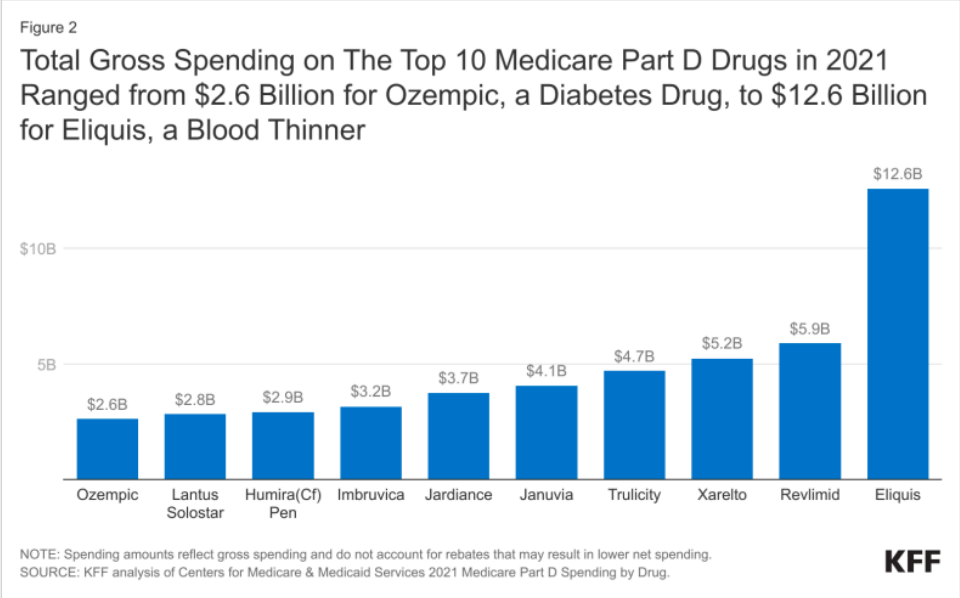
One Drug, Eylea—Which Is Used To Treat The Eye Condition Known As Macular Degeneration Affecting Older Adults—Was Granted A Staggering 90 Patents Including One On The Sterilization Of The Packaging, Has Blocked The Generic Competitors For The $1,800-A-Dose Drug. "A perfect poster child for undeserving patents is Regeneron's product Eylea, which treats an eye condition known as macular degeneration that affects older adults. Eylea was approved by the U.S. Food and Drug Administration in 2011 and thanks to over 90 granted patents—including one for minor adjustments to its sterile packaging—the drug is unlikely to see any generic competitors for years to come. Today, the list price for a single dose of Eylea in the U.S. is over $1,800, while it costs roughly half that amount in the UK." [TIME, 02/24/23]

- **Headline: Big Pharma's Patent Abuses Are Fueling the Drug Pricing Crisis.** [TIME, 02/24/23]

In 2021 Alone, Eliquis, Revlimid, Xarelto, Trulicity, Januvia, Jardiance, Imbruvica, Humira, Lantus And Ozempic Accounted For About 22% Of Spending By Medicare Part D On Prescription Drugs, A Total Of Over $46.8 Billion.

In 2021, Eliquis, Revlimid, Xarelto, Trulicity, Januvia, Jardiance, Imbruvica, Humira, Lantus And Ozempic Accounted For Over $46.8 Billion In Medicare Part D Spending On Prescription Drugs.

According To Data Collected By KFF, The Prescription Drugs Eliquis, Revlimid, Xarelto, Trulicity, Januvia, Jardiance, Imbruvica, Humira, Lantus And Ozempic Accounted For Over $46.8 Billion In Medicare Part D Spending In 2021:



(KFF)

[Fierce Healthcare, 07/13/23]

The 10 Drugs Accounted For About 22% Of Medicare Part D Spending In 2021. "Approximately 22% of gross Medicare Part D spending can be attributed to 10 top-selling prescription drugs, according to analysis from KFF. The 10 drugs made up less than 1% of all covered drugs in 2021, and all were brand-name drugs,

the study found. In 2021, Part D covered 3,500 prescription drugs, with total gross spending of $216 billion." [Fierce Healthcare, 07/13/23]

Bristol Myers Squibb

Bristol Myers Squibb (BMS) And Pfizer Hold Key Patents On Blood Thinner Eliquis—Prescribed To Over 3.5 Million Part D Enrollees As Of 2022—Set To Expire From 2027 To 2029, With The Drug Making The Company A Staggering $11.8 Billion In Sales In 2022 Alone.

Bristol Myers Squibb (BMS) And Pfizer Manufacture The Blood Thinner Eliquis, Which Is Used To Prevent Strokes And To Treat Patients Suffering From Atrial Fibrillation, Was Prescribed To Over 3.5 Million Medicare Part D Enrollees In 2022.

Eliquis, Manufactured By Bristol Myers Squibb And Pfizer, Is Used To Treat Stroke Victims And Those Suffering From Atrial Fibrillation. [Eliquis, accessed 03/19/24]

- **Eliquis Is Manufactured By Bristol Myers Squibb And Pfizer.** [Eliquis, accessed 02/01/24]

In 2022, Over 3.5 Million Medicare Part D Enrollees Were Prescribed Eliquis:

Drug Name	Commonly Treated Conditions	Total Number of Medicare Part D Enrollees Taking the Drug in CY2022[a]		
		LIS	Non-LIS	Total
Eliquis	Prevention and treatment of blood clots	1,013,000	2,492,000	3,505,000

[Department of Health and Human Services, 08/29/23]

According To A February 2024 Study By Bentley University, The NIH Spent $791 Million Of Taxpayer Money Funding The Development Of Eliquis. [The Lever, 02/22/24]

Bristol Myers Increased The Cost Of Its Drug Eliquis By 43 Percent Between 2018 And 2022, With The Drug's Price Set To Be Negotiated With Medicare.

According To HHS, Between 2018 And 2022, The Cost Of Eliquis—Which Is Manufactured By Bristol Myers—Increased By 43 Percent, With 3.5 Million Medicare Enrollees Requiring The Medication. "Between 2018 and 2022, average annual total Part D spending per enrollee taking Eliquis (i.e., the total amount, including Medicare, plan, and enrollee payments, spent on Eliquis per person) increased by 43 percent (from $3,031 to $4,342. [...] About 3.5 million Part D enrollees filled prescriptions for Eliquis in 2022." [Department of Health and Human Services, 10/30/23]

- **Eliquis Is Manufactured By Bristol Myers Squibb And Pfizer.** [Eliquis, accessed 02/01/24]

Bristol Myers Patent For Eliquis Is Set To Expire In 2026, Which Made Up Nearly $11.8 Billion Of Its Sales In 2022, As The Company Sued Generics Alleging Patent Infringement In An Effort To Block Them From Entering The Marketplace.

Bristol Myers' Eliquis, A Blood Thinner Used To Prevent Clotting, Is Set To Have Its Patent Expire In 2026 And Accounted For A Quarter Of Its Sales In 2022 At Nearly $11.8 Billion:

Bristol Myers Squibb's Eliquis is a blood thinner used to prevent clotting, to reduce the risk of stroke.

- Key patent expirations: 2026 to 2028
- 2022 sales: $11.79 billion
- Percentage of company's total 2022 sales: Around 25%
- Estimated future revenue: $478 million in 2032, according to Leerink Partners estimates.

[CNBC, 01/28/24]

In April 2023, Pfizer And BMS, Which Jointly Own Patents On Eliquis, Sued Generics From Entering The Marketplace Alleging They Would Infringe On Their Patent For The Medication, Which Are Set To Expire In 2027 Through 2029.

April 2023: Pfizer And BMS Sued To Block Generics Of Eliquis From Entering The Marketplace, Alleging They Would Infringe On Their Patent For The Medication. [Bloomberg Law, 04/10/23]

Eliquis Has Key Patents Set To Expire From 2027 To 2029:

2. ELIQUIS

Company: Bristol Myers Squibb & Pfizer

Key patent expirations: 2027 to 2029

Eliquis (Apixaban) is a medicine used to prevent blood clots in adults. Approved for medical use in the European Union in May 2011, and in the United States in December 2012, Eliquis has become one of the most effective treatment options for DVT and PE.

[Proclinical, 02/16/24]

BMS's Revlimid—Which Is Cancer Treatment Drug Taken By 45,601 Medicare Patients As Of 2021—Has Faced A Lawsuit From Mayo Clinic And LifePoint Health Alleging BMS Subsidiary Celgene Had Pressured Other Companies To Delay Producing Lower-Cost Generic Cancer Drugs.

Revlimid Is A Cancer Treatment Drug That Is Used To Treat Cancer Patients Going Through Chemotherapy And Was Used By 45,601 Medicare Patients In 2021.

Revlimid Is Manufactured By Bristol Myers Squibb And Used To Treat Patients With Cancer. [Revlimid, accessed 03/19/24]

According To Medicare And Medicaid Data Collected By Kaiser Family Foundation, There Were 45,601 Medicare Patients On Revlimid In 2021:

- **Revlimid**: 45,601 users in 2021; average total Part D spending per beneficiary = $129,242

[Kaiser Family Foundation, 10/20/23]

Celgene And Bristol Myers Faced An October 2023 Lawsuit Brought By The Mayo Clinic And LifePoint Health After The Companies Allegedly Conspired With Other Drug Companies To Delay The Production Of A Generic Version Of Revlimid.

October 2023: The Mayo Clinic And LifePoint Health Filed A Lawsuit Against Celgene And Its Parent Company Bristol-Myers Squibb For Conspiring With Other Drug Companies To Delay The Production Of A Generic Version Of Its Drug Revlimid In What It Described As A "Pay For Delay" Scheme. "The Mayo Clinic and LifePoint Health believe that collusion within the pharmaceutical industry forced their organizations to overpay for the multiple myeloma drug Revlimid and are petitioning the court to recover the funds. Earlier this month, the health systems filed a 146-page lawsuit in the U.S. District Court for the Northern District of California against Revlimid manufacturer Celgene and its parent company Bristol-Myers Squibb (BMS), as well as drugmakers Natco Pharma, Teva Pharmaceuticals and Dr. Reddy's Laboratories. The complaint alleges that Revlimid's rights holders conspired with the latter group of drugmakers to limit and delay their production of a generic version of Revlimid—what the systems described as 'pay for delay' settlement agreements." [Fierce Healthcare, 10/19/23]

- **Celgene Is A Subsidiary Of Bristol-Myers Squibb.** [Celgene, accessed 01/30/24]

Celgene And BMS Allegedly Were Able To Coerce Competitors Into Not Launching Generics In Certain Dosage Strengths And Even Delaying Supplying The Market With Generic Alternatives Until 2026. "In exchange for dropping its patent lawsuits against the other drug makers and ceding a portion of the market for the treatment, Celgene and BMS allegedly secured arrangements in which the other defendants chose not to launch their generics in certain dosage strengths. Some of these alleged agreements keep the other defendants from fully supplying the market with a generic until 2026, according to the lawsuit." [Fierce Healthcare, 10/19/23]

Bristol Myers Squibb—Represented On PhRMA's Board Of Directors—Filed Its Own Lawsuit In Court Challenging The IRA's Medicare Drug Price Negotiation Provision Claiming It Violated The First And Fifth Amendments, With Its Former CEO Writing An August 2023 Opinion Piece Claiming It Would Lead To The Development Of Fewer Drugs.

In June 2023, The Pharmaceutical Research And Manufacturers Of America (PhRMA)—Big Pharma's Largest Trade Group And Lobbying Arm With BMS Represented On Its Board—Sued The Biden Administration Over Its Medicare Drug Price Negotiation Provision.

June 2023: The Pharmaceutical Research And Manufacturers Of America (PhRMA)—Big Pharma's Largest Trade Group And Lobbying Arm—Sued The Biden Administration Over The Inflation Reduction Act's Medicare Price Negotiation Provision. "The pharmaceutical industry's largest lobbying group and two other organizations sued the Biden administration over Medicare's new powers to slash drug prices for seniors under the Inflation Reduction Act. Pharmaceutical Research and Manufacturers of America, the National

Infusion Center Association and the Global Colon Cancer Association argue that the Medicare negotiations violate the U.S. Constitution, in a complaint filed in federal district court in Texas." [CNBC, 06/21/23]

Bristol Myers CEO Chris Boerner Is On PhRMA's Board Of Directors:

Chris Boerner, PhD

Chief Executive Officer

BMS

[Pharmaceutical Research And Manufacturers of America, accessed 01/29/24]

Bristol Myers Squibb Also Filed Its Own Lawsuit In June 2023 Alleging The IRA's Drug Price Negotiation Provisions Violated The First And Fifth Amendments.

June 2023: Bristol Myers Squibb Also Filed Its Own Lawsuit Challenging The Inflation Reduction Act Claiming It Violated The Constitution, Alleging The IRA Violated The First And Fifth Amendments. "After Merck filed a bombshell lawsuit challenging some measures in the Inflation Reduction Act (IRA), Bristol Myers Squibb has followed on with a case of its own. The New York-based pharma giant took the same approach as Merck, questioning the constitutionality of some aspects of the law. Specifically, BMS alleges that the IRA's price-setting facets, which allow Medicare to negotiate and set prices for certain drugs, violate the First and the Fifth Amendments of the U.S. Constitution." [Fierce Pharma, 06/20/23]

In August 2023, Former Bristol Myers CEO Giovanni Caforio Claimed The Inflation Reduction Act's Medicare Negotiation Provision Did Not "Involve Any Negotiation In Any Ordinary Sense Of The Word," Claiming It Would Lead To The Development Of Fewer Drugs And "Signal That Industry Should Walk Away From Medicines For The Elderly."

August 2023: Former Bristol Myers CEO Giovanni Caforio Wrote An Op-Ed In Which He Claimed The Inflation Reduction's Act Medicare Price Negotiation Provision Did Not "Involve Negotiation In Any Ordinary Sense Of The Word" And Claimed It Would Cause Pharmaceutical Companies To "Withdraw" Medicines Under Medicare And Medicaid. "Eliquis is now in the news again. It is among the first 10 medicines subject to 'negotiations' under the Inflation Reduction Act to determine what Medicare will pay for it. Contrary to how it has been framed, the Inflation Reduction Act's drug-pricing program doesn't involve negotiation in any ordinary sense of the word. If drug developers disagree with the dictated price, our only options are to pay impossibly high penalties or withdraw our medicines from Medicare and Medicaid." [The Wall Street Journal, 08/29/23]

Caforio Further Claimed It Would "Discourag[e] The Development Of Oral Drugs" And Would "Sen[d] A Signal That Industry Should Walk Away From Medicines For The Elderly." "The law will end up discouraging the development of oral drugs that help millions of elderly patients in the U.S. That's because the Inflation Reduction Act arbitrarily offers less protection to 'small molecule' medicines, including those taken in a pill or capsule, than to 'large molecule' injected or infused medicines, thus penalizing the development of treatments that are more convenient for patients. It also targets treatments that help many older Americans, sending a signal that industry should walk away from medicines for the elderly." [The Wall Street Journal, 08/29/23]

Since Q1 2023, Bristol Myers Squibb Has Spent Over $9.4 Million While Lobbying On Issues Related To Implementing The Inflation Reduction Act, H.R. 4895 The Lowering Drug Costs For American Families Act, The 340B Drug Pricing Program, And Other Issues.

Since Q1 2023, Bristol Myers Squibb Spent Over $9.4 Million While Lobbying On Issues Related To Implementation Of The Inflation Reduction Act, The 340B Drug Pricing Program, Among Other Issues.

Since Q1 2023, Bristol Myers Squibb Spent Over $9.4 Million While Lobbying On Issues Related To Implementation Of The Inflation Reduction Act, The 340B Drug Pricing Program, And H.R. 4895 The Lowering Drug Costs For American Families Act, Among Other Issues:

Registrant	Lobbying Period	Relevant Lobbying Issues	Amount
Bristol Myers Squibb	Q1 2024	H.R.4895, Lowering Drug Costs for American Families Act; Implementation of Inflation Reduction Act of 2022; Issues related to the 340B Drug Pricing Program - regarding all bio-pharmaceutical related provisions	$600,000
Bristol Myers Squibb	Q4 2023	Issues related to the 340B Drug Pricing Program - regarding all bio-pharmaceutical related provisions Inflation Reduction Act implementation	$2,060,000
Bristol Myers Squibb	Q3 2023	Issues related to the 340B Drug Pricing Program - regarding all bio-pharmaceutical related provisions Inflation Reduction Act implementation	$2,180,000
Bristol Myers Squibb	Q2 2023	Issues related to the 340B Drug Pricing Program - regarding all bio-pharmaceutical related provisions Issues related to the Inflation Reduction Act of 2022 IRA implementation	$2,230,000
Bristol Myers Squibb	Q1 2023	HR 5376, the Build Back Better Act regarding all bio-pharmaceutical provisions; Issues related to the 340B Drug Pricing Program - regarding all bio-pharmaceutical related provisions Issues related to the Inflation Reduction Act of 2022 IRA implementation	$2,410,000
		TOTAL:	**$9,480,000**

- **H.R. 4895 The Lowering Drug Costs For American Families Act Was Introduced By U.S. House Energy & Commerce Ranking Member Frank Pallone Jr. (D-NJ) And Would Extend Drug Price Negotiation To Private Insurers, Bar Drug Companies From Hiking Drugs Higher Than Inflation And Increase The Number Of Drugs Set To Be Negotiated From 20 To 50.** [Rep. Frank Pallone, Jr., 07/26/23]

Johnson & Johnson

Johnson & Johnson Subsidiary Janssen Pharmaceuticals, Along With Bayer, Manufacture The Blood Thinner Xarelto, Which Medicare Spent Over $5.8 Billion For In 2022, With At Least 1.3 Million Medicare Enrollees Needing The Drug.

Xarelto, A Blood Thinner Made By Johnson & Johnson Subsidiary Janssen, Was Prescribed To At Least 1.3 Million Medicare Enrollees In 2022, While Medicare Spent $5.8 Billion For The Drug In 2022, With The NIH Spending $764 Million Of Taxpayer Money Funding The Drug's Development.

Xarelto Is A Blood Thinner Manufactured By Janssen Pharmaceuticals, A Subsidiary Of Johnson & Johnson, And By Bayer AG. [Xarelto, accessed 03/19/24]

- **Janssen Pharmaceuticals Is A Subsidiary Of Johnson & Johnson.** [Janssen Pharmaceuticals, accessed 03/21/24]
- **Bayer AG Manufactures Xarelto Alongside Johnson & Johnson.** [Reuters, 03/25/19]
- **Xarelto Is A Blood Thinner.** "For example, the blood thinner Xarelto is covered in tablet form for virtually all Part D enrollees, but the share of enrollees with coverage of the oral suspension falls to 78%." [Kaiser Family Foundation, 09/26/23]

According To Medicare And Medicaid Data, Over 1.3 Million Medicare Part D Enrollees In 2022:

Xarelto	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	370,000	941,000	1,311,000

[Department of Health and Human Services, 08/29/23]

In 2022, Medicare Part D Spent $5.8 Billion On Xarelto, Up From $5.2 Billion In 2021. [Kaiser Family Foundation, 03/22/24]

Xarelto Is Also One Of The First Ten Medications Set To Be Negotiated With Medicare. [Department of Health and Human Services, 09/13/23]

And According To A February 2024 Study By Bentley University, The NIH Spent $764 Million Of Taxpayer Money Funding The Development Of Xarelto. [The Lever, 02/22/24]

Xarelto Patent Holders Janssen And Bayer Have Filed Lawsuits To Block Generics From Entering The Marketplace, Alleging Attempts To Use The Drug Rivaroxaban Would Infringe Upon Patents Not Set To Expire Until 2039, With A UK Court Ruling Bayer's Patent On The Drug Was "Invalid" In April 2024, In A Move That Could Allow Competitors To Introduce Generics In The European Market.

In December 2021, Janssen And Bayer—Joint Holders Over A Rivaroxaban Patent On Xarelto—Filed Five Lawsuits In U.S. Court Against Attempts To Introduce Generics, With A UK Court Ruling In April 2024 That Bayer's Patent Was "Invalid," Clearing The Way For Generic Versions Of The Drug.

Janssen Pharmaceuticals And Bayer—Which Own Patents On Xarelto—Filed Five Patent Lawsuits Challenging Competitors Over Efforts To Make Generic Versions Of The Drug, Alleging "The Generics Would Infringe A Patent On A Method Of Using The Drug's Active Ingredient, Rivaroxaban, In Combination With Aspirin, Set To Expire In 2039." "The Judicial Panel on Multidistrict Litigation on Friday consolidated five patent lawsuits filed by Bayer AG and Janssen Pharmaceuticals Inc seeking to block generic versions of their blockbuster stroke prevention drug Xarelto. [...] Johnson & Johnson subsidiary Janssen, which sells Xarelto in the United States, and Bayer, which sells it elsewhere, sued all the generic companies after they filed applications with the Food and Drug Administration seeking to make generic versions of the drug. Such preemptive infringement lawsuits are allowed under the Hatch-Waxman Act. [...] They claim that the generics would infringe a patent on a method of using the drug's active ingredient, rivaroxaban, in combination with aspirin, set to expire in 2039." [Reuters, 12/10/21]

April 2024: Bayer Was Struck A Massive Blow To Its Patent For Xarelto In The United Kingdom Where A Court Ruled Its Patent On Xarelto As "Invalid," "Pav[ing] The Way For Other Drug Makers To Launch Generic Versions Of Rivaroxaban." "Bayer's patent covering its best-selling blood thinner Xarelto is invalid, London's High Court ruled on Friday in a blow to the German drugmaker. [...] Its European patent over once-daily rivaroxaban, with a brand name of Xarelto, has now been declared invalid following legal challenges brought by Sandoz and other rival manufacturers. [...] Friday's decision paves the way for other drug makers to launch generic versions of rivaroxaban, though Bayer said it would be seeking to block such attempts pending any appeal." [Yahoo! Finance, 04/12/24]

Xarelto's Key Patent Is Set To Expire In 2026:

6. XARELTO

Company: Bayer / J&J

Key patent expiration: 2026

Patented in 2007 and approved for medical use in the United States in 2011, Xarelto (Rivaroxaban) is used to treat and prevent blood clots. The anticoagulant, which was jointly developed by Bayer and J&J's Janssen Pharmaceuticals (now Innovative Medicines), has been prescribed more than 80 million times in the US alone. In 2022, it was Bayer's bestselling pharmaceutical product, bringing in €4,516 million worth of revenue.

[Proclinical, 02/16/24]

Johnson & Johnson Is A Member Of The Pharmaceutical Research And Manufacturers Of America (PhRMA)—Which Filed A June 2023 Suit Challenging The Biden Administration's Drug Price Negotiation Provision—Later Becoming The Third Major Pharmaceutical Company To File A Suit In July 2023.

In June 2023, The Pharmaceutical Research And Manufacturers Of America (PhRMA)—Big Pharma's Largest Trade Group And Lobbying Arm With Johnson & Johnson Represented On Its Board—Sued The Biden Administration Over Its Medicare Drug Price Negotiation Provision.

June 2023: The Pharmaceutical Research And Manufacturers Of America (PhRMA)—Big Pharma's Largest Trade Group And Lobbying Arm—Sued The Biden Administration Over The Inflation Reduction

Act's Medicare Price Negotiation Provision. "The pharmaceutical industry's largest lobbying group and two other organizations sued the Biden administration over Medicare's new powers to slash drug prices for seniors under the Inflation Reduction Act. Pharmaceutical Research and Manufacturers of America, the National Infusion Center Association and the Global Colon Cancer Association argue that the Medicare negotiations violate the U.S. Constitution, in a complaint filed in federal district court in Texas." [CNBC, 06/21/23]

Johnson & Johnson Executive Vice President And Worldwide Chairman Jennifer Taubert Is On The PhRMA Board Of Directors:

[Pharmaceutical Research and Manufacturers of America, accessed 01/23/24]

In July 2023, Johnson & Johnson Became The Third Pharmaceutical Company To Sue The Biden Administration Over Its Medicare Drug Price Negotiation Mandate.

July 2023: "Johnson & Johnson Sued The Biden Administration Over Medicare's New Powers To Slash Drug Prices, Making It The Third Pharmaceutical Company To Challenge The Controversial Provision Of The Inflation Reduction Act." "Johnson & Johnson sued the Biden administration over Medicare's new powers to slash drug prices, making it the third pharmaceutical company to challenge the controversial provision of the Inflation Reduction Act. [...] Earlier suits brought separately by Merck and Bristol Myers Squibb, as well as by the U.S. Chamber of Commerce and PhRMA, the pharmaceutical industry's largest lobbying group, made similar arguments." [CNBC, 07/18/23]

Since Q1 2023, Johnson & Johnson Spent Over $9.5 Million While Lobbying On Issues Relating To 340B, Implementation Of The Inflation Reduction Act, Biosimilars, And Other Issues.

Since Q1 2023, Johnson & Johnson Spent Over $9.5 Million While Lobbying On Issues Related To Implementation Of The Inflation Reduction Act, The 340B Program, Medicaid Rebates, And Other Issues.

Since Q1 2023, Johnson & Johnson Spent Over $9.5 Million While Lobbying On Issues Related To Implementation Of The Inflation Reduction Act And The 340B Program, Among Other Issues:

Registrant	Lobbying Period	Relevant Lobbying Issues	Amount
Johnson & Johnson	Q1 2024	L 117-169, "The Inflation Reduction Act", regarding provisions impacting drug pricing and implementation; 340B; Biosimilars; Issues related to the Medicaid Drug Rebate Program.	$2,730,000
Johnson & Johnson	Q4 2023	PL 117-169, "The Inflation Reduction Act", regarding provisions impacting drug pricing and implementation; -	$1,160,000

		340B	
Johnson & Johnson	Q3 2023	PL 117-169, "The Inflation Reduction Act", regarding provisions impacting drug pricing and implementation; - 340B	$2,350,000
Johnson & Johnson	Q2 2023	PL 117-169, "The Inflation Reduction Act", regarding provisions impacting drug pricing and implementation; - 340B	$850,000
Johnson & Johnson	Q1 2023	PL 117-169, "The Inflation Reduction Act", regarding provisions impacting drug pricing and implementation; - 340B	$2,490,000
		TOTAL:	**$9,580,000**

Eli Lilly And Company

Eli Lilly & Company Manufactures The Type 2 Diabetes Drug Trulicity, Which Medicare Part D Spent $6.2 Billion On In 2022 With A Key Patent Set To Expire In 2027.

Trulicity, Which Is Manufactured By Eli Lilly To Treat Type 2 Diabetes, Saw $6.2 Billion In Medicare Part D Spending In 2022 And Has A Key Patent Expiring In 2027.

Trulicity Is Manufactured By Eli Lilly And Is Used To Treat Type 2 Diabetes. [Trulicity, accessed 03/19/24]

In 2022, Medicare Spent $6.2 Billion On The Drug Trulicity:

Drug	2022
[...]	
Trulicity	$6.2B

[Kaiser Family Foundation, 03/22/24]

In 2027, A Key Patent For Eli Lilly's Insulin Drug Trulicity Is Set To Expire.

Trulicity Has A Key Patent Set To Expire In 2027:

7. TRULICITY

Company: Eli Lilly

Key patent expiration: 2027

Trulicity, which comes in injection form, is used for the treatment of type 2 diabetes in adults and children over the age of 10 years. It works to reduce the risk of major cardiovascular complications in adult patients.

Approved in 2014, Trulicity is protected by a compound patent until 2027, when the floodgates will open to generic completion. After losing patent protections on two of its biggest stars, anti-depressant Cymbalta and osteoporosis treatment Evista, Eli Lilly desperately needed Trulicity to be a success when it was launched 10 years ago. Since then, Trulicity has become one of Eli Lilly's biggest sources of revenue and it was the 17th bestselling drug in the world in 2023.

[Proclinical, 02/16/24]

In 2022, Eli Lilly's Jardiance Was Prescribed To Over 1.3 Million Americans On Medicare, With The Type 2 Diabetes Medication Costing Medicare Nearly $6 Billion In 2022, With The Drug Set To Be One Of The First Ten Drugs To Be Negotiated.

In 2022, Eli Lilly's Jardiance, Which Is Used To Treat Type 2 Diabetes, Heart Failure And Kidney Disease, Was Prescribed To Over 1.3 Million People On Medicare, While Medicare Spent $5.9 Billion For Jardiance In 2022.

Jardiance Is Manufactured By Eli Lilly And Is Used To Treat Type 2 Diabetes And Recently Approved By The FDA To Treat Chronic Kidney Disease. [Eli Lilly, 09/22/23]

In 2022, Over 1.3 Million Medicare Part D Enrollees Were Prescribed Jardiance:

Jardiance	Diabetes; Heart failure	562,000	759,000	1,321,000

[Department of Health and Human Services, 08/29/23]

- **According To The Department Of Health And Human Services, Approximately 28% Of Medicare Enrollees Have Diabetes.** [Department of Health and Human Services, 11/07/23]

In 2022, Medicare Spent $5.9 Billion For Jardiance:

Drug	2022
[...]	
Jardiance	$5.9B

[Kaiser Family Foundation, 03/22/24]

Jardiance Is Also One Of The First Ten Medications Set To Be Negotiated With Medicare. [Department of Health and Human Services, 09/13/23]

In August 2023, Nine States Warned Against A Proposed Settlement With Eli Lilly Over An Insulin Price-Fixing Class Action Lawsuit Arguing It Would Shield The Company From Future Suits, Before Eli Lilly And Other Companies Walked Back On The Agreement.

In August 2023, Nine States Warned Against A Proposed Settlement With Eli Lilly Over An Insulin Price-Fixing Class Action Lawsuit, Arguing It Would Shield The Company From Future Suits, Before Eli Lilly And Other Companies Walked Back On The Agreement.

August 2023: Nine States Objected To A Proposed $13.5 Million Settlement With Insulin Manufacturers, Including Eli Lilly And Company, Alleging It Would Shield It From Future Lawsuits Over Insulin Price-Fixing. "Nine U.S. states are objecting to a proposed $13.5 million settlement between Eli Lilly and Co (LLY.N), and a class of insulin buyers over claims that it inflated the drug's price, saying the drugmaker is

wrongly trying to use the deal to shield itself from future lawsuits by states. In a filing, on Tuesday in Newark, New Jersey, federal court, lawyers for Arizona, Mississippi and Minnesota urged U.S. District Judge Brian Martinotti to delay final approval of the deal until it is changed to make sure that states can still sue over insulin prices." [Reuters, 08/16/23]

Plaintiffs In A Class Action Suit Alleged Lilly Alongside Competitors Sanofi And Novo Nordisk Inflated The Price Of Insulin Drugs While Offering Steep Discounts For Pharmacy Benefit Managers (PBMs) And Forcing Patients To Pay More Out Of Pocket Costs. "People who paid out-of-pocket cost for Lilly's insulin drug Humalog accused the company, along with competitors Sanofi and Novo Nordisk, of inflating the drug's list price while offering steep discounts to the pharmacy benefit managers (PBMs) that determine what drugs are available through insurance plans. That created an incentive for the PBMs to keep listing the drugs despite the ballooning prices, while forcing patients to pay more, the plaintiffs said." [Reuters, 08/16/23]

States Also Alleged Eli Lilly Forced Language Into The Settlement That Would Prevent Attorneys General From Being Able To File Future Suits On Behalf Of Their Citizens, With A Separate Filing From Six States Alleging "Lilly Was Trying To Settle Claims Valued At About $1 Billion For Something That It Was Already Compelled By Law To Provide." "While the lawsuit has been pending, the federal Inflation Reduction Act capped out-of-pocket insulin costs for Medicaid beneficiaries at $35, and many states have capped it at $35 or less. Arizona, Mississippi and Minnesota said that Lilly refused to add language to the settlement making clear that state attorney generals will still have the right to sue on behalf of their citizens. In a separate filing Monday, the other six states also argued that, since they had all already capped insulin costs at $35 or less, Lilly was trying to settle claims valued at about $1 billion for something that it was already compelled by law to provide." [Reuters, 08/16/23]

However, In April 2024, Eli Lilly And Other Plaintiffs Walked Out Of Its Settlement Deal, Which Would Have Forced Eli And Co-Plaintiffs To Pay $13.5 Million And Cap Out-Of-Pocket Costs For Insulin At $35 A Month. "Almost a year after originally proposing a $13.5 million settlement to end years of litigation relating to alleged insulin overpricing, Eli Lilly and plaintiffs in the nationwide class-action lawsuit have walked back the deal. Attorneys on Friday inked a letter to New Jersey District Court Judge Brian Martinotti on behalf of the company and the plaintiffs, informing the court that the two are terminating the settlement agreement and therefore not going through with the associated preliminary approval process. Along with the $13.5 million, the settlement agreement would have included a $35 out-of-pocket cap on monthly insulin costs for four years." [Fierce Pharma, 04/17/24]

The Move Followed Another Ruling From A Federal Judge Who "Opted Against Certifying Certain State-Specific Classes In The Case," With Eli Lilly Saying The Move "Reaffirmed" Its Position That "Insulin Pricing Suits Lack Merit." "The move follows a recent ruling (PDF) in which the judge opted against certifying certain state-specific classes in the case. Fellow insulin makers Novo Nordisk and Sanofi are entangled in the same litigation. According to Lilly, the decision “reaffirmed what Lilly has said all along: these insulin pricing suits lack merit,” a spokesperson said in an emailed statement." [Fierce Pharma, 04/17/24]

Since Q1 2023, Eli Lilly Has Spent Over $9.6 Million While Lobbying On The Inflation Reduction Act, Legislation Aimed At Bringing Down The Costs Of Insulin And Issues Related To Intellectual Property And Patent Protections.

Since Q1 2023, Eli Lilly Has Spent Over $9.6 Million While Lobbying On The Inflation Reduction Act, Legislation Aimed At Bringing Down The Costs Of Insulin And Issues Related To Intellectual Property And Patent Protections.

Since Q1 2023, Eli Lilly Has Spent Over $9.6 Million While Lobbying On The Inflation Reduction Act, Legislation Aimed At Bringing Down The Costs Of Insulin And Issues Related To Intellectual Property And Patent Protections:

Registrant	Lobbying Period	Relevant Lobbying Issues	Amount
Eli Lilly	Q1 2024	Drug pricing; Implementation of the "Inflation Reduction Act"; Affordable Insulin Now Act (S.954/HR.1488)	$1,730,000
Eli Lilly	Q4 2023	Issues related to intellectual property protection and market access within current trade negotiation; Implementation of the "Inflation Reduction Act" (HR.5376); Affordable Insulin Now Act (S.3700/HR.6833)	$2,530,000
Eli Lilly	Q3 2023	Issues related to intellectual property protection and market access within current trade negotiation; Implementation of the "Inflation Reduction Act" (HR.5376); Affordable Insulin Now Act (S.3700/HR.6833)	$2,301,360
Eli Lilly	Q2 2023	Issues related to intellectual property protection and market access within current trade negotiation; Implementation of the "Inflation Reduction Act" (HR.5376); Affordable Insulin Now Act (S.3700/HR.6833)	$1,585,000
Eli Lilly	Q1 2023	Drug pricing; Implementation of the "Inflation Reduction Act" (HR.5376); Affordable Insulin Now Act (S.3700/HR.6833)	$1,470,000
		TOTAL:	**$9,616,360**

- **S. 954 "The Affordable Insulin Now Act" Is A Bi-Partisan Piece Of Legislation Introduced By Sen. John Kennedy (R-LA) And Sen. Raphael Warnock (D-GA) That Would Cap The Monthly Cost Of Insulin At $35.** [Sen. John Kennedy, 03/23/23]

Merck

Merck-Manufactured Januvia, Which Is Used To Treat Type 2 Diabetes, Was Prescribed To 885,000 Medicare Part D Enrollees In 2022, Charging Medicare $4.1 Billion In 2022.

Merck-Manufactured Januvia, Which Is Used To Treat Type 2 Diabetes, Was Prescribed To At Least 885,000 Medicare D Enrollees In 2022, With Medicare Spending $4.1 Billion On The Drug In 2022, Which The NIH Spent $228 Million Of Taxpayer Money To Develop The Drug.

Januvia Is Manufactured By Merck And Is Used To Treat Type 2 Diabetes. [Januvia, accessed 03/19/24]

In 2022, 885,000 Medicare Part D Enrollees Were Prescribed Januvia:

Januvia	Diabetes	426,000	459,000	885,000

[Department of Health and Human Services, 08/29/23]

- **According To The Department Of Health And Human Services, Approximately 28% Of Medicare Enrollees Have Diabetes.** [Department of Health and Human Services, 11/07/23]

In 2022, Medicare Spent $4.1 Billion On Januvia:

Drug	2022
[...]	
Januvia	$4.1B

[Kaiser Family Foundation, 03/22/24]

Januvia Is Also One Of The First Ten Medications Set To Be Negotiated With Medicare. [Department of Health and Human Services, 09/13/23]

And According To A February 2024 Study By Bentley University, The NIH Spent $228 Million Of Taxpayer Money Funding The Development Of Januvia. [The Lever, 02/22/24]

In 2022, Merck Won A Key Battle Over A Januvia Patent That Was Set To Expire On Januvia In Early 2023, When A Court Sided With The Drug Maker Over Generics, With Merck Telling Investors "It Expects To Maintain U.S. Market Exclusivity On Januvia Until May 2026."

In 2022, Merck Won A Key Battle Over A Januvia Patent That Was Set To Expire In Early 2023, When A Court Sided With The Drug Maker Over Generics, With Merck Telling Investors "It Expects To Maintain U.S. Market Exclusivity On Januvia Until May 2026."

Despite Originally Having A Patent Set To Expire In Early 2023, Merck Was Approved A Secondary Patent To Extend Its Hold On The Diabetes Marketplace, Further Staving Off Competition After It Was Granted A Victory By A Court In A Lawsuit Alleging Patent Infringement, With The Company Reaching 26 Settlement Agreements With Generic Manufacturers Hoping To Introduce Biosimilars Of Its Drugs Januvia And Janumet. "The pharmaceutical giant's key U.S. intellectual property on the active ingredient in Januvia was set to expire in early 2023, and rivals started gearing up to launch low-cost copies — an outcome that would almost certainly drive down the drug's price and offer consumers more choices. But, as happens so often in the pharmaceutical industry, the owner of the brand-name drug was able to stave off the competition with the help of a secondary patent. That additional legal protection helped Merck prevail in a high-stakes court fight last year. Separately, the company has reached 26 settlement agreements with generic manufacturers that have sought to market their own versions of Januvia and Janumet, another Merck drug that uses the same key ingredient." [The Philadelphia Inquirer, 12/20/23]

After These Victories, Merck Told Its Shareholders "It Expects To Maintain U.S. Market Exclusivity On Januvia Until May 2026" Even When Regulators In Europe And China Approved Less-Expensive Generics. "As a result, Merck, the biggest employer in Montgomery County, has told investors it expects to maintain U.S. market exclusivity on Januvia until about May 2026, even as regulators in Europe and China have approved less-expensive copies known as generic drugs. That three years of extra protection for Merck could mean an additional $3.5 billion in U.S. revenue, according to one estimate. Research shows a drug's price can drop as much as 20% when the first generic hits the market — and as much as 85% after multiple alternatives are approved." [The Philadelphia Inquirer, 12/20/23]

Since 2006, Merck Has Hiked The Price OF Januvia By 275%, Currently Charging Americans 5.5 Times More Than Customers In Canada And Over 20 Times More Than Customers In Germany. "Januvia costs significantly more in the U.S. than in other high-income countries. For example, Merck charges U.S. customers 5.5x more than customers in Canada, and over 20x more to U.S. customers than to customers in Germany. Januvia has increased in price by 275 percent since its launch in 2006." [Protect Our Care, accessed 04/24/24]

Merck—Which Sits On The Board Of PhRMA—Filed Its Own Lawsuit In June 2023 Challenging The IRA's Medicare Drug Pricing Negotiation Arguing The Law Violated The Fifth Amendment And That The Government Wanted To "Take Merck's Patented Innovations By Coercing The Company To Provide Third Parties With Access At Prices The Government Sets."

In June 2023, The Pharmaceutical Research And Manufacturers Of America (PhRMA)—Big Pharma's Largest Trade Group And Lobbying Arm With Merck Represented On Its Board—Sued The Biden Administration Over Its Medicare Drug Price Negotiation Provision.

June 2023: The Pharmaceutical Research And Manufacturers Of America (PhRMA)—Big Pharma's Largest Trade Group And Lobbying Arm—Sued The Biden Administration Over The Inflation Reduction Act's Medicare Price Negotiation Provision. "The pharmaceutical industry's largest lobbying group and two other organizations sued the Biden administration over Medicare's new powers to slash drug prices for seniors under the Inflation Reduction Act. Pharmaceutical Research and Manufacturers of America, the National Infusion Center Association and the Global Colon Cancer Association argue that the Medicare negotiations violate the U.S. Constitution, in a complaint filed in federal district court in Texas." [CNBC, 06/21/23]

Merck President And CEO Robert M. Davis Sits On PhRMA's Board Of Directors:

Robert M. Davis

Chief Executive Officer and President

Merck & Co., Inc.

[Pharmaceutical Research And Manufacturers of America, accessed 01/29/24]

Prior To PhRMA's Lawsuit Challenging The IRA, Merck Filed Its Own Lawsuit Claiming The Medicare Drug Pricing Negotiation Provision Violated The Fifth Amendment And Would Lead To The Government "Tak[ing] Merck's Patented Innovations By Coercing The Company To Provide Third Parties With Access."

June 2023: Merck Filed A Lawsuit Against The IRA's Medicare Drug Negotiation Provision, Claiming The Law Was Unconstitutional And Would Lead To "Devastating Consequences For Millions Of Patients In Need." "Unfortunately, this progress is now at risk due to unconstitutional provisions in the Inflation Reduction Act (IRA), necessitating the legal action Merck has taken in U.S. Federal Court against the United States government. We believe this program will negatively impact biopharmaceutical innovation and the

sector's work to develop lifesaving and life-changing innovations. In turn, it will have devastating consequences for millions of patients in need." [Merck, 06/06/23]

Merck Sued The Biden Administration On The Grounds The IRA Allegedly Violated The Fifth Amendment And Would Lead To The Government "Tak[ing] Merck's Patented Innovations By Coercing The Company To Provide Third Parties With Access At Prices The Government Sets." "As we detail in our complaint, the Fifth Amendment requires the U.S. government pay 'just compensation' if it takes property for public use. However, the IRA allows the government to obtain innovations without providing fair value for them. Under the IRA, the government will take Merck's patented innovations by coercing the company to provide third parties with access at prices the government sets." [Merck, 06/06/23]

Since Q1 2023, Merck Spent Over $12.1 Million While Lobbying On Issues Related To H.R. 3 Elijah E. Cummings Lower Drug Costs Now Act, The Inflation Reduction Act, And Issues Related to Patent And Trademark Laws, Among Others.

Since Q1 2023, Merck Spent Over $12.1 Million While Lobbying On Issues Related To H.R. 3 Elijah E. Cummings Lower Drug Costs Now Act, The Inflation Reduction Act, And Issues Related to Patent And Trademark Laws, Among Other Issues.

Since Q1 2023, Merck Spent Over $12.1 Million While Lobbying On Issues Related To H.R. 3 Elijah E. Cummings Lower Drug Costs Now Act, The Inflation Reduction Act, And Issues Related To Patent And Trademark Laws, Among Others:

Registrant	Lobbying Period	Relevant Lobbying Issues	Amount
Merck	Q1 2024	H.R. 3, (117th Cong.) Elijah E. Cummings Lower Drug Costs Now Act; H.R. 4895, Lowering Drug Costs for American Families Act; 340B drug pricing program	$2,190,000
Merck	Q4 2023	H.R. 3, (117th Cong.) Elijah E. Cummings Lower Drug Costs Now Act; Inflation Reduction Act (P.L. 117-169), provisions relating to budget reconciliation and taxes; Issues related to the Patent and Trademark Law Amendments Act (PL 96-517); 340B drug pricing program;	$1,940,000
Merck	Q3 2023	H.R. 3, (117th Cong.) Elijah E. Cummings Lower Drug Costs Now Act; Inflation Reduction Act (P.L. 117-169); Issues related to the Patent and Trademark Law Amendments Act (PL 96-517); 340B drug pricing program;	$2,130,000
Merck	Q2 2023	H.R. 3, (117th Cong.) Elijah E. Cummings Lower Drug Costs Now Act; Inflation Reduction Act (P.L. 117-169); Issues related to the Patent and Trademark Law Amendments Act (PL 96-517); 340B drug pricing program;	$2,980,000
Merck	Q1 2023	H.R. 3, (117th Cong.) Elijah E. Cummings Lower Drug Costs Now Act; Inflation Reduction Act (P.L. 117-169); Issues related to the Patent and Trademark Law Amendments Act (PL 96-517); 340B drug pricing program;	$2,930,000
		TOTAL:	**$12,170,000**

- **H.R. 4895 "The Lowering Drug Costs For American Families Act" Was Introduced By U.S. House Energy & Commerce Ranking Member Frank Pallone Jr. (D-NJ) And Would Extend Drug Price Negotiation To Private Insurers, Bar Drug Companies From Hiking Drugs Higher Than Inflation And Increase The Number Of Drugs Set To Be Negotiated From 20 To 50.** [Rep. Frank Pallone, Jr., 07/26/23]

- **H.R. 3 "The Elijah E. Cummings Lower Drug Costs Now Act" Was Introduced In April 2021 And Would Increase The Number Of Drugs The Department Of Health And Human Services Could Negotiate With Drug Manufacturers That Make Up The 125 Drugs That Makes Up Most Of National Medicare Spending.** "In particular, the bill requires the Department of Health and Human Services (HHS) to negotiate prices for certain drugs (current law prohibits HHS from doing so). Specifically, HHS must negotiate maximum prices for single-source, brand-name drugs that lack certain generics and that are among either the 125 drugs that account for the greatest national spending or the 125 drugs that account for the greatest Medicare spending. [Congress.gov, accessed 04/23/24]

AbbVie

AbbVie-Manufactured Cancer Treatment Imbruvica Is Prescribed To At Least 22,000 Medicare Enrollees As Of 2022, While Medicare Spent $3.1 Billion For The Drug In 2021, As The Drug Is Set To Be One Of The Ten Drugs In Negotiation With Medicare.

In 2022, AbbVie-Manufactured Cancer Treatment Imbruvica Was Prescribed To At Least 22,000 Medicare Part D Enrollees, With Medicare Spending $3.1 Billion For Imbruvica In 2021, With The Drug Being Negotiated With Medicare.

Imbruvica Is Manufactured By AbbVie And Is Used To Treat Patients Undergoing Chemotherapy. [Imbruvica, accessed 03/19/24]

In 2022, 22,000 Medicare Part D Enrollees Were Prescribed Imbruvica:

Imbruvica	Blood cancers	4,000	18,000	22,000

[Department of Health and Human Services, 08/29/23]

In 2021, Medicare Spent $3.2 Billion On Imbruvica:

Drug	2021 ▲
[...]	
Imbruvica	$3.2B

[Kaiser Family Foundation, 03/22/24]

Imbruvica Is Also One Of The First Ten Medications Set To Be Negotiated With Medicare. [Department of Health and Human Services, 09/13/23]

AbbVie's Rheumatoid Arthritis And Crohn's Disease Medication Humira Was Prescribed To At Least 42,000 Medicare Enrollees In 2020, With Medicare Spending At Least $3.7 Billion For The Drug In 2022.

AbbVie's Drug Humira, Which Is Used To Treat Patients With Rheumatoid Arthritis And Crohn's Disease, Was Prescribed To 42,000 Medicare Enrollees In 2020, With Medicare Spending $3.7 Billion For The Drug In 2022.

Humira Is A Drug Manufactured By AbbVie And Is Used To Treat Rheumatoid Arthritis And Crohn's Disease. [Humira, accessed 03/20/24]

In 2020, Humira Was Taken By About 42,000 Patients Enrolled In Medicare. "One analysis found that Medicare, which in 2020 covered the cost of Humira for 42,000 patients, spent $2.2 billion more on the drug from 2016 to 2019 than it would have if competitors had been allowed to start selling their drugs promptly. In interviews, patients said they either had to forgo treatment or were planning to delay their retirement in the face of enormous out-of-pocket costs for Humira." [The New York Times, 01/28/23]

Medicare Spent $3.7 Billion For Humira In 2022:

Drug	2022
[...]	
Humira(Cf) Pen	$3.7B

[Kaiser Family Foundation, 03/22/24]

In March 2023, The Department Of Health And Human Services Ordered AbbVie To Pay Back Medicare For "Hiking Prices Faster Than Inflation" For Its Drug Humira.

March 2023: The Department Of Health And Human Services Said That AbbVie's Humira Was One Of 27 Drugs That Had To Repay Medicare For "Hiking Prices Faster Than Inflation." "The Department of Health and Human Services (HHS) has unveiled the first set of Medicare Part B prescription drugs that must repay the program for raising prices above inflation in the last quarter of 2022. A new HHS report released Wednesday outlines the products—including AbbVie's blockbuster arthritis drug Humira—that must pay Medicare back for hiking prices faster than inflation. Officials said the goal in part is to send a message to other drug companies." [Fierce Health, 03/15/23]

In January 2023, AbbVie's Monopoly On Humira Finally Ended After Seven Drugs Were Set To Enter The Marketplace, After AbbVie Earned A Staggering $208 Billion In Global Revenue From Humira From 2002 To 2022.

In January 2023, AbbVie's Monopoly On Humira Finally Ended After Seven Drugs Were Set To Enter The Marketplace, Including A Biosimilar Manufactured By Amgen, With AbbVie Successfully Filing 165 Patents On The Drug, Which Earned It A Staggering $208 Billion In Global Revenue From 2002 To 2022.

A January 2023 Report By The New York Times Notes That AbbVie's Humira Exploited The U.S. Patent System For Years, With The Drug Producing Over $114 Billion In Revenue Just Since The End Of 2016. "Through its savvy but legal exploitation of the U.S. patent system, Humira's manufacturer, AbbVie, blocked competitors from entering the market. For the next six years, the drug's price kept rising. Today, Humira is the most lucrative franchise in pharmaceutical history. Next week, the curtain is expected to come down on a monopoly that has generated $114 billion in revenue for AbbVie just since the end of 2016." [The New York Times, 01/28/23]

AbbVie And Other Patent Holders Filed 311 Patent Applications Related To Humira, With 165 Of Those Being Granted. "AbbVie and its affiliates have applied for 311 patents, of which 165 have been granted, related to Humira, according to the Initiative for Medicines, Access and Knowledge, which tracks drug patents. A vast majority were filed after Humira was on the market." [The New York Times, 01/28/23]

- **Headline: How a Drug Company Made $114 Billion by Gaming the U.S. Patent System.** [The New York Times, 01/28/23]

On January 31, 2023, Competitor Amgen Finally Released Its Version Of The Rheumatoid Arthritis Drug, With Seven More Humira Generics Expected To Debut By The End Of 2023. "After 20 years and $200 billion in revenue, Humira — an injectable treatment for rheumatoid arthritis and several other autoimmune conditions — has lost its monopoly. Early Tuesday morning, California-based biotech firm Amgen released Amjevita, the first close copy of the best selling drug of all time. At least seven more Humira copycats, known as biosimilars, are expected to debut later this year." [National Public Radio, 01/31/23]

- **Headline: AbbVie's blockbuster drug Humira finally loses its 20-year, $200 billion monopoly.** [National Public Radio, 01/31/23]

Humira Earned AbbVie A Staggering $208 Billion In Global Revenue Since It Was Approved To Treat Rheumatoid Arthritis In 2002, With 2021 Sales Making Up Over A Third Of The Company's Revenue. "Humira has earned $208 billion globally since it was first approved in 2002 to ease the symptoms of rheumatoid arthritis. It has since been authorized to treat more autoimmune conditions, including Crohn's disease and ulcerative colitis. Patients administer it themselves, typically every week or two, injecting it with a pen or syringe. In 2021, sales of Humira accounted for more than a third of AbbVie's total revenue." [The New York Times, 01/28/23]

Since Q1 2023, AbbVie Has Spent Over $5.2 Million While Lobbying On S. 142 The Preserve Access To Affordable Generics And Biosimilars Act, Issues Related To Intellectual Property, The 340B Rebate Program, And Medicare Part D Drug Negotiations, Among Other Issues.

Since Q1 2023, AbbVie Spent Over $5.2 Million While Lobbying On Issues Related To Intellectual Property, 340B Program, Medicare Part D Drug Negotiations, And Against S. 142 The Preserve Access To Affordable Generics And Biosimilars Act, Among Other Issues.

Since Q1 2023, AbbVie Spent Over $5.2 Million While Lobbying On Issues Related To Intellectual Property, 340B Program, And Medicare Part D Drug Negotiations, Among Other Issues:

Registrant	Lobbying Period	Relevant Lobbying Issues	Amount
AbbVie	Q1 2024	S.142, Preserve Access to Affordable Generics and Biosimilars Act; Public Law 117-169 (formerly known as H.R. 5376, Inflation Reduction Act) Implementation regarding Medicare Part D drug negotiation program and smoothing out-of-pocket costs for patients	$1,590,000
AbbVie	Q4 2023	S.142, Preserve Access to Affordable Generics and Biosimilars Act; Value of intellectual property; Issues related to the 340B program; Drug cost and pricing policy issues; Implementation regarding Medicare Part D drug negotiation program	$830,000
AbbVie	Q3 2023	S.142, Preserve Access to Affordable Generics and Biosimilars Act; Value of intellectual property; Issues related to the 340B program; Drug cost and pricing policy issues; Implementation regarding Medicare Part D drug negotiation program	$750,000
AbbVie	Q2 2023	S.142, Preserve Access to Affordable Generics and Biosimilars Act; Value of intellectual property; Issues related to the 340B program; Drug cost and pricing policy issues; Implementation regarding Medicare Part D drug negotiation program	$600,000
AbbVie	Q1 2023	S.142, Preserve Access to Affordable Generics and Biosimilars Act; Value of intellectual property; Issues related to the 340B program; Drug cost and pricing policy issues; Implementation regarding Medicare Part D drug negotiation program	$1,500,000
		TOTAL:	**$5,270,000**

- **S. 142 The Preserving Access to Affordable Generics And Biosimilars Act Would Limit Pharma's Use Of '"Pay-For-Delay Deals"' That Prevent Or Delay Generic Brands Of A Medication From Entering The Marketplace.** "The Preserving Access to Affordable Generics and Biosimilars Act would limit anticompetitive “pay-for-delay deals” that prevent or delay the introduction of affordable follow-on or generic versions of branded pharmaceuticals. The legislation covers pay-for-delay deals affecting biosimilar and interchangeable biologics in addition to generic drugs." [Sen. Chuck Grassley, 02/09/23]

Sanofi

Lantus Solostar, An Insulin Medication Manufactured By Sanofi, Was Prescribed To 1.1 Million Medicare D Enrollees In 2017, With Sanofi Charging Medicare At Least $2.9 Billion For The Drug In 2022.

Lantus Solostar, Used As An Insulin Medication, Was Prescribed To At Least 1.1 Million Part D Enrollees In 2017, With Medicare Spending $2.9 Billion For The Drug In 2022.

Lantus Solostar Is An Insulin Medication Manufactured By Sanofi. [Lantus, accessed 03/20/24]

In 2017, 1.1 Million Part D Enrollees Were Prescribed Lantus Solostar. "Among all insulin products, Part D spending was highest for Lantus Solostar, a long-acting insulin manufactured by Sanofi, with $2.6 billion in Part D spending in 2017. This one drug alone, used by 1.1 million Part D enrollees in 2017, accounted for 20% of total Part D spending on insulin that year." [Kaiser Family Foundation, 04/01/19]

- **According To The Department Of Health And Human Services, Approximately 28% Of Medicare Enrollees Have Diabetes.** [Department of Health and Human Services, 11/07/23]

Medicare Spent $2.9 Billion For Lantus Solostar In 2022, Up Slightly From $2.8 Billion In 2021:

Drug	2022
Lantus Solostar	$2.9B

[Kaiser Family Foundation, 03/22/24]

Sanofi Has Aggressively Opposed Efforts From Competing Firms To Introduce Generic Versions Of Lantus, Including A Legal Fight With Mylan Over Patent Infringement—With Mylan Accusing Sanofi Of A "Multifaceted Monopolization Scheme" By Submitting "Invalid" And "Unfringed" Patents In An Effort To Delay Generics From Entering The Marketplace.

In 2021, Sanofi Was Defeated In Federal Court After A Patent Board Denied Its Efforts To "Revive Parts Of Patents Relates To Its Lantus SoloStar Insulin Pens," With Sanofi Accusing Competitor Mylan Of Attempting To Make A Generic Version Of The Medication, Which Earned Sanofi Over $3 Billion In Sales In 2020.

December 2021: A U.S. Appeals Court Rejected A Challenge By Sanofi To "Revive Parts Of Patents Related To Its Lantus SoloStar Insulin Pens" After Drug Maker Mylan Successfully Challenged Patents Before The Patent Trial And Appeal Board. "U.S. appeals court on Wednesday rejected a bid by a Sanofi SA unit to revive parts of patents related to its Lantus SoloStar insulin pens, after generic drugmaker Mylan Pharmaceuticals Inc successfully challenged the patents at the Patent Trial and Appeal Board. The three rulings, by the U.S. Court of Appeals for the Federal Circuit move Mylan closer to being able to make a generic version of the pens, and follow a New Jersey court decision, invalidating a related Sanofi patent last year." [Reuters, 12/29/21]

Sanofi Had Sued Mylan In 2020, Accusing The Company Of Patent Infringement After It Proposed Its Generic Version Of Lantus, Which Made Sanofi Over $3 Billion In Sales In 2020 Alone. "Sanofi sued Mylan for patent infringement in that case over its proposed generic version of the SoloStar device, used to deliver its insulin drug Lantus. Sanofi reported that it sold more than $3 billion worth of Lantus worldwide in 2020. Mylan, now part of Canonsburg, Pennsylvania-based Viatris Inc, filed 10 petitions in 2020 asking the PTAB to review five patents covering aspects of France-based Sanofi's device." [Reuters, 12/29/21]

In November 2023, The Federal Trade Commission (FTC) Supported An Antitrust Lawsuit From Mylan Pharmaceuticals Challenging The "Monopolization Scheme" That Sanofi Waged By Allegedly Submitting "Invalid" And "Uninfringed" Patents To The FDA In Order To Delay The Approval Of Generics.

November 2023: The Federal Trade Commission (FTC) Weighed In On An Antitrust Lawsuit Brought By Mylan Pharmaceuticals Against Sanofi Over Its Insulin Pen Lantus, With The Agency Alleging That Sanofi Abused The FDA's Patent Regulatory Process. "The U.S. Federal Trade Commission (FTC) isn't letting up in its effort to crack down on pharma's alleged misuse of a patent mechanism in the FDA's regulatory process. And it's Sanofi's turn to land in the crosshairs. The FTC is weighing in on an antitrust lawsuit that Viatris' Mylan brought against Sanofi in May centered on the French pharma's popular insulin product Lantus. Although the agency didn't pick sides in the case, it's using the lawsuit as an opportunity to criticize the type of behavior accused of Sanofi." [Fierce Pharma, 11/21/23]

Mylan Accused Sanofi Of Operating A "'Multifaceted Monopolization Scheme"' To Protect Its Profits From Lantus, Alleging Sanofi Even Submitted "Invalid" And "Uninfringed" Patents To Delay The Approval Of Generics. "In the lawsuit, Mylan accused Sanofi of running a 'multifaceted monopolization scheme' to protect Lantus. One of the alleged illegal practices involves entering in the Orange Book a 'thicket of invalid and/or uninfringed patents' to delay the approval of biosimilars, according to Mylan's complaint." [Fierce Pharma, 11/21/23]

Since Q1 2023 Sanofi Spent Over $7.5 Million While Lobbying On Issues Related To Intellectual Property, Medicare Negotiations And The 340B Drug Rebates Program, Among Other Issues Impacting Prescription Drugs Pricing.

Since Q1 2023, Sanofi Spent Over $7.5 Million While Lobbying On Issues Related To Intellectual Property, Medicare Negotiation, 340B, Medicaid Drug Rebates, And Other Issues Affecting Prescription Drug Pricing.

Since Q1 2023, Sanofi Spent Over $7.5 Million While Lobbying On Issues Related To IP, Medicare Negotiation, 340B, Medicaid Drug Rebates, And Other Issues Affecting Prescription Drug Pricing:

Registrant	Lobbying Period	Relevant Lobbying Issues	Amount
Sanofi US	Q1 2024	Issues related to intellectual property; Issues related to Medicare Negotiations; issues related to drug pricing negotiations; issues related to 340B; issues related to Medicaid Drug Rebate Program rule	$2,160,000
Sanofi US	Q4 2023	Issues related to intellectual property; Issues related to Medicare Negotiations; issues related to drug pricing negotiations; issues related to 340B; issues related to Medicaid Drug Rebate Program rule	$880,000
Sanofi US	Q3 2023	Issues related to intellectual property; Issues related to Medicare Negotiations; issues related to drug pricing negotiations; issues related to 340B	$1,520,000
Sanofi US	Q2 2023	Issues related to intellectual property; Issues related to Medicare Negotiations; issues related to drug pricing negotiations; issues related to 340B	$1,120,000

Sanofi US	Q1 2023	Issues related to intellectual property; Issues related to Medicare Negotiations; issues related to drug pricing negotiations; issues related to 340B	$1,860,000
		TOTAL:	**$7,540,000**

Novo Nordisk

Novo Nordisk—Maker Of The Insulin Medication Ozempic And Europe's Highest Valued Company As Of September 2023—Charged Medicare $4.6 Billion For The Drug In 2022, While 500,000 Medicare Enrollees Were Prescribed The Medication.

Insulin Injection Medication Ozempic, Which Is Manufactured By Novo Nordisk, Was Prescribed To About 500,000 Part D Enrollees In 2021 Costing Medicare $2.6 Billion, A 76% Increase YoY.

Ozempic Is An Insulin Injection Developed By Novo Nordisk To Treat Type 2 Diabetes. [Ozempic, accessed 03/20/24]

In 2021, About 500,000 Medicare Part D Enrollees Were Prescribed Ozempic, Totaling $2.6 Billion In Medicare Spending. "Gross Part D spending on Ozempic, used by 0.5 million Part D enrollees in 2021, totaled $2.6 billion." [Kaiser Family Foundation, 07/12/23]

- **According To The Department Of Health And Human Services, Approximately 28% Of Medicare Enrollees Have Diabetes.** [Department of Health and Human Services, 11/07/23]

In 2021, Medicare Spent $2.6 Billion For Ozempic, With Medicare Spending For The Drug Increasing By 76% To $4.6 Billion Just A Year Later In 2022. [Kaiser Family Foundation, 03/22/24]

In October 2023, Novo Nordisk—Which Became Europe's Highest Valued Company In September 2023—Squashed A Challenge By Mylan Pharmaceuticals In An Attempt To Begin Manufacturing A Generic Version Of Ozempic.

October 2023: The U.S. Patent Office Rejected Challenges To Novo Nordisk, Which Holds Patents On Ozempic, While Drugmaker Mylan Hoped To Produce A Generic Version Of Ozempic. "U.S. Patent Office tribunal on Monday rejected challenges to two key patents owned by Novo Nordisk (NOVOb.CO), covering the active ingredient in its weight-loss and diabetes drugs Wegovy and Ozempic brought by a generic drugmaker that is hoping to sell generic versions of the blockbuster medications. The office's Patent Trial and Appeal Board denied the requests by Mylan Pharmaceuticals, which is owned by Viatris (VTRS.O), to review the validity of the Wegovy and Ozempic patents." [Reuters, 10/02/23]

- **The Argument Was Lost By Mylan Pharmaceuticals Who Is Taking On The Challenge Against Novo Nordisk.** "Mylan Pharmaceuticals Inc. persuaded a US Patent and Trademark Office administrative tribunal to take up one of its challenges to Novo Nordisk A/S patents linked to the lucrative weight-loss drugs Ozempic and Wegovy." [Bloomberg Law, 10/04/23]

"Mylan Had Argued The Patents Were Obvious Based On The Anti-Diabetes Medication Liraglutide And Thus Should Be Invalidated." "The office's Patent Trial and Appeal Board denied the requests by Mylan

Pharmaceuticals, which is owned by Viatris (VTRS.O), to review the validity of the Wegovy and Ozempic patents. Mylan had argued that the patents were obvious based on the anti-diabetes medication liraglutide and thus should be invalidated." [Reuters, 10/02/23]

Record Profits From Ozempic Caused Denmark-Based Novo Nordisk To Climb To The Highest-Valued European Company In September 2023. "Record profits from Wegovy and type 2 diabetes drug Ozempic - which contains the same active ingredient, semaglutide - helped Denmark-based Novo become Europe's most valuable company in September." [Reuters, 10/02/23]

However, The Board Did Agree To Look At Novo Nordisk's Patent No. 10,335,462 , Which Isn't Set To Expire Until June 2033. "The PTAB instituted IPR of Novo Nordisk's US Patent No. 10,335,462 on Wednesday, saying Mylan sufficiently argued that some of the patent's claims were likely anticipated by and obvious in light of previous inventions. The patent is scheduled to expire in June 2033, Bloomberg Law estimates." [Bloomberg Law, 10/04/23]

Novo Nordisk—Who Sits On The PhRMA Board Of Directors—Filed Its Own Lawsuit Challenging The IRA's Medicare Drug Price Negotiation Provision In September 2023 Joining Other Companies Claiming It Violated The First And Fifth Amendments Calling It "Price Controls."

In June 2023, The Pharmaceutical Research And Manufacturers Of America (PhRMA)—Big Pharma's Largest Trade Group And Lobbying Arm With Novo Nordisk Represented On Its Board—Sued The Biden Administration Over Its Medicare Drug Price Negotiation Provision.

June 2023: The Pharmaceutical Research And Manufacturers Of America (PhRMA)—Big Pharma's Largest Trade Group And Lobbying Arm—Sued The Biden Administration Over The Inflation Reduction Act's Medicare Price Negotiation Provision. "The pharmaceutical industry's largest lobbying group and two other organizations sued the Biden administration over Medicare's new powers to slash drug prices for seniors under the Inflation Reduction Act. Pharmaceutical Research and Manufacturers of America, the National Infusion Center Association and the Global Colon Cancer Association argue that the Medicare negotiations violate the U.S. Constitution, in a complaint filed in federal district court in Texas." [CNBC, 06/21/23]

Novo Nordisk Executive Vice President Of North American Operations Douglas J. Langa Sits On The PhRMA Board Of Directors

Douglas J. Langa
Executive Vice President
North America Operations
and President
Novo Nordisk Inc

[Pharmaceutical Research and Manufacturers of America, accessed 04/23/24]

In September 2023, Novo Nordisk Filed Its Own Lawsuit Challenging The Inflation Reduction Act's Medicare Price Negotiation, Claiming It Was Unlawful "Price Controls" That Violated The First And Fifth Amendments.

September 2023: Novo Nordisk Filed Its Own Lawsuit Challenging The Medicare Drug Price Negotiation Provisions Of The IRA, Filing Similar Claims The Law Violated The First And Fifth Amendments. "Novo Nordisk has joined the long list of biopharma companies that are challenging drug price negotiation provisions in the Inflation Reduction Act (IRA). Novo filed a lawsuit in federal district court in New Jersey on Friday, claiming that the program violates the First Amendment and the Fifth Amendment. Novo's suite of insulin treatments for diabetes, including NovoLog and Fiasp, are among 10 drugs subject to Centers for Medicare & Medicaid Services (CMS) price negotiations in 2026. The insulin products accounted for $2.6 billion in Medicare Part D spending from June 2022 to May 2023, according to CMS data. [Fierce Pharma, 10/02/23]

Novo Also Likened The Law To Unlawful "Price Controls." "In its lawsuit, Novo claims that the CMS has "unlawfully deemed" six of its insulin treatments as a single biologic product subject to "price controls." [Fierce Pharma, 10/02/23]

Since Q1 2023, Novo Nordisk Spent Over $6.4 Million While Lobbying On Insulin Pricing, Patent Protection And IRA Implementation.

Since Q1 2023, Novo Nordisk Spent Over $6.4 Million While Lobbying On Insulin Pricing, Patent Protection And IRA Implementation, Among Other Issues.

Since Q1 2023, Novo Nordisk Spent Over $6.4 Million While Lobbying On Insulin Pricing, Patent Protection And IRA Implementation, Among Other Issues:

Registrant	Lobbying Period	Relevant Lobbying Issues	Amount
Novo Nordisk	Q1 2024	Insulin Pricing/ affordability; Intellectual Property; patent protection; IRA Implementation	$2,180,000
Novo Nordisk	Q4 2023	Insulin Pricing/ affordability; Intellectual Property; patent protection; IRA Implementation	$1,440,000
Novo Nordisk	Q3 2023	Insulin Pricing/ affordability; Intellectual Property; patent protection; IRA Implementation	$600,000
Novo Nordisk	Q2 2023	Insulin Pricing/ affordability; Intellectual Property; patent protection; IRA Implementation	$846,120
Novo Nordisk	Q1 2023	Insulin Pricing/ affordability; Intellectual Property; patent protection; IRA Implementation	$1,343,495
		TOTAL:	**$6,409,615**