PUBLICCITIZEN

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Dear Ranking Member Wyden and colleagues,

Thank you for your initiative exploring policy options to lower prices and improve prescription drug affordability for people in the United States.

Public Citizen is a consumer advocacy organization with more than 1,000,000 members and supporters and a fifty-year history protecting the public's interest before federal agencies, Congress, and the courts. The Access to Medicines program advocates for access to prescription drugs in the United States and internationally. As such, we and our members have a strong interest in improving affordable and stable access to vital medications for U.S. patients.

We urge you to build on the Inflation Reduction Act with policies to save hundreds of billions of dollars in prescription drug costs and make sure all Americans have access to the medicines they need. By ensuring pharmaceutical corporations charge no more for prescriptions in the United States than they do in Europe or Canada and capping out-of-pocket costs, we can end pharma rip-offs and treatment rationing.

Big Pharma's monopolistic price gouging is worse now than at any time in American history. It has become intolerable and unsustainable, with four-in-ten Americans rationing medicines they need because they are too expensive.[i] Annual drug spending now exceeds half a trillion dollars and is projected to reach more than $800 billion in 2034.[ii]

Congressional Democrats and the Biden-Harris Administration made the first major progress in a generation by empowering Medicare to negotiate the prices for some older medicines with high annual spending, establishing penalties for price spikes, and putting in place protections in Medicare Part D from excessive out-of-pocket costs. Already the negotiation program is saving patients and taxpayers billions of dollars annually[iii] and out-of-pocket limits are helping to lower cost-related nonadherence,[iv] but according to the Congressional Budget Office, in part due to the combination of 1) Medicare price negotiations and inflation rebates having less impact and 2) the Part D redesign and out-of-pocket cap costing significantly more than anticipated, Medicare drug spending will be even greater than what was anticipated before the Inflation Reduction Act was passed.[v] The scale of our drug pricing crisis demands bold solutions.

Senators and members of Congress should advance three policies into law to provide all Americans access to medicines at fair, affordable prices:

1) **Negotiate the prices on all brand name prescription drugs;**
2) **Limit negotiated prices based on what drug companies charge in other high-income countries; and**
3) **Extend the benefits of negotiations, price spike protections and improved out-of-pocket caps to the private market.**

The comments below will first focus on policies surrounding these three proposals as well as reply to other issues presented in the request for information (RFI), including reforms to the drug supply chain and support for biomedical innovation.

Negotiating Prices on All Branded Drugs

Exemptions from negotiations---expanded by congressional Republicans' and President Trump's Big Ugly Bill---inappropriately exclude drugs on which Medicare and patients spend tens of billions of dollars annually, while drug corporations are spiking drug launch prices to new heights year after year. Drug companies argue that exemptions and delays from negotiation are necessary to allow a return on investment, but in reality, independent research and development cost estimates are significantly lower than industry-cited estimates that use opaque data sets.[vi] Even at lower negotiated prices paid in other countries, pharmaceuticals remain extremely lucrative due to low marginal costs of production.[vii]

The negative impacts of negotiation exemptions and delays are profound. Negotiation delay periods mean that patients and taxpayers are forced to pay higher, unnegotiated prices for nearly a decade or longer before the government is allowed to step in and negotiate. Of the drugs selected for the current round of price negotiations, Medicare already spent more than $70 billion from 2012 through 2023 yet negotiated prices will be unavailable until 2028.[viii] Meanwhile, the median launch price charged by pharmaceutical companies for a new drug in the United States jumped from $2,115 in 2008 to $180,007 in 2021, a 20 percent annual inflation rate.[ix] In 2025, the median price was $216,000 (an artificially low number due to the mix of drugs approved last year).[x]

Moreover, long negotiation delays mean that even when drugs otherwise qualify for negotiation, they may still never have a negotiated price as generic or biosimilar competition may come on the market before or during the negotiation period. One drug selected this year in the third round of the program, Xeljanz / Xeljanz XR, will never have a negotiated price in place due to generics entering the market, despite the time and government resources spent on negotiation.[xi] Under current policy, Medicare is unable to select an alternative product to

negotiate in its place, foregoing potential savings. In other cases, Medicare and its beneficiaries may only benefit from one year of a lower negotiated price before a drug is deselected from the program, as will be the case with three of the 10 drugs selected in the first round of the program, Entresto, Stelara, and Xarelto.[xii]

The orphan drug exemption should also be eliminated entirely. Proponents of the exemption argue it is needed to preserve innovation for rare disease treatments, but the United States already provides robust support for research and development of treatments for rare diseases, and this loophole is shielding from negotiations expensive drugs on which Medicare spends billions of dollars annually. To support and provide incentive for rare disease treatments, currently the FDA grants prescription drug companies developing products to prevent, diagnose or treat a rare disease or condition with orphan drug designations, which qualifies the product sponsors with tax credits covering up to 25% of eligible clinical trial expenses, an exemption from user fees, and the potential to receive seven years of marketing exclusivity for orphan indications after approval.[xiii] Analysts found that of the $2.1 trillion Medicare Part B and D spent on drugs from 2012 through 2021, $77 billion was spent on sole orphan drugs, $108 billion on drugs with multiple orphan indications, and $75 billion on drugs first approved with an orphan indication and subsequently approved for a non-orphan indication.[xiv] Another recently published analysis found that drugs delayed or exempted from negotiation through the orphan exemption and the One Big Beautiful Bill Act are at no economic disadvantage relative to drugs that do not qualify for the orphan exemption and delay.[xv]

Other high-income countries with long-established frameworks and the U.S. Department of Veterans Affairs negotiate the prices of brand name drugs soon after approval, with most negotiating the prices of all newly approved brand-name drugs without exclusions.[xvi] No delay periods or orphan drug exemptions were envisaged in the legislative antecedent to the Inflation Reduction Act, the Elijah E. Cummings Lower Drug Costs Now Act, which all House Democrats voted to pass in the 116th Congress.[xvii]

We urge policymakers to pass reforms to remove exemptions and require Medicare to negotiate prices of all brand name drugs at launch and increase the number of currently approved drugs it negotiates to at least 50 per year until all currently approved, costly medicines have negotiated prices in place. Additionally, once a negotiated price is established for a medicine, it should remain in place. This is necessary for program integrity to ensure drug companies cannot evade negotiated prices on new forms of a drug when an older version of the same drug faces generic competition.

A large majority of voters across the political spectrum want Medicare to negotiate lower prices on all the drugs it currently buys.[xviii] Doing so would rapidly produce tens of billions of dollars in savings while reducing out-of-pocket costs for patients.[xix]

Limiting Negotiated Prices Based on International Prices

The United States pays 3-4 times more for prescription drugs than other rich countries.[xx] Even for products that have undergone Medicare negotiation, prices charged by prescription drug companies in the United States remain significantly higher than those in other large, high-income countries,[xxi] and negotiations are lowering prices less than initially projected.[xxii] Pharmaceutical spending now accounts for nearly 3% of gross domestic product (GDP) of the entire U.S. economy, compared to around 1.2% of GDP for non-US Organisation for Economic Co-operation and Development (OECD) countries, driven in large part by higher U.S. prices.[xxiii]

Public Citizen supports incorporating an international reference price-based ceiling into the Medicare drug price negotiation program. Limiting negotiated prices based on the prices paid in other countries is the most direct and surefire way to ensure that U.S. prices are no longer wildly out of step with prices paid in peer nations. We encourage policymakers to incorporate several key features into an international reference price-based ceiling or other policy, to promote fairness and help prevent negative externalities in countries resulting from pharma attempts at gaming:

- Limit reference countries to those with the largest gross domestic products, per capita incomes at least 50% of the United States, and large pharmaceutical markets.
- Calculate the ceiling based on the median price or a volume-weighted average of prices across reference countries.
- Adjust ex-U.S. prices by a ratio of reference country per capita income to U.S. per capita income when calculating the ceiling.
- Empower the Secretary to make a good faith effort at estimating confidential discounts when that information is not available through manufacturer submissions or other public data, a practice that is utilized in other countries that incorporate international pricing information for pharmaceutical reimbursement. For example, in Germany officials use their own estimate if manufacturer submitted information on confidential discounts is not credible and France "mobilizes intelligence" to estimate secret discounts in other countries.[xxiv] If the Secretary is unable to estimate confidential discounts on a product, it could also be empowered to apply an estimate based on product class and indication.

Americans across partisan and demographic groups overwhelmingly support (by an 86% - 8% margin) allowing Medicare to negotiate all of the drugs it purchases paying no more than what drugs sell for in other wealthy countries.[xxv] By establishing a ceiling for Medicare price negotiations based on prices in other high-income countries, policymakers can finally deliver Americans fair prices and produce tens of billions of dollars in annual savings.[xxvi]

Extending Negotiated Prices, Price Spike Protections, and Improved Out-of-Pocket Limits Beyond Medicare

More than 200 million American obtain their health insurance coverage through private plans.[xxvii] People who get their insurance through their employer or the Affordable Care Act marketplace do not directly benefit from Medicare price negotiations or price spike protections and remain potentially exposed to significantly higher out-of-pocket costs.[xxviii]

Of the $400 billion in drug expenditures covered by insurance in 2024, more than 40% was through private insurance.[xxix] Private insurance drug prices are even higher than those realized by Medicare and other government health programs,[xxx] and thus potentially even greater savings to Americans could be produced through extending access to prices established through Medicare price negotiations to people with private insurance. Researchers estimate that if prices realized in other high-income countries were available across the U.S. market, it would save close to $200 billion annually.[xxxi] Like an international price-based ceiling, the House-passed Elijah E. Cummings Lower Drug Costs Now Act included a mechanism to offer Medicare-negotiated prices to people who get insurance through their employer or the Affordable Care Act.

The impact of Medicare rebate protections against price spikes is currently uncertain, as commercial sales are excluded from rebate calculations.[xxxii] By including commercial sales in Medicare inflation rebate calculations, as well as Part B drug units sold through Medicare Advantage, policymakers can ensure that these price spike protections have their intended impact in Medicare while shielding people with private health insurance coverage from drug companies' price increases. Additionally, we urge rebasing penalties to the date a product first enters the market; unjustified price increases that occurred before a certain date are no less inappropriate than those that occurred in recent years.

The most direct way patients are financially impacted by exorbitant prescription drug prices is through their out-of-pocket costs as copays or coinsurance. Within Medicare, lowering the annual OOP cap would ensure that millions more seniors and people with disabilities are provided with relief from high drug costs. Additionally, expanding eligibility to the low-income subsidy will help seniors and people with disabilities most vulnerable to high drug costs get the medicines they need. The Improving Medicare Act includes measures to expand

eligibility for additional support to beneficiaries with incomes up to 200% of the Federal Poverty Line. While we also support policies to cap cost-sharing for particular types of drugs, like the insulin cap that was included in the Inflation Reduction Act, we recognize policymakers likely will be forced to make tradeoffs between those measures and lowering annual out-of-pocket caps or improving subsidies for low-income beneficiaries. Given these choices, we urge greater out-of-pocket relief that does not preference patients with one disease or condition over another who also face high out-of-pocket costs, so we urge prioritization of lowering the annual out-of-pocket cap and expanding low-income subsidy eligibility over product-specific caps. Ideally, policymakers should pursue an out-of-pocket cap that is not limited to Part D and protects patients from catastrophic health care costs across traditional Medicare.

Beyond Medicare, more than half of Americans who have self-purchased or employer-sponsored insurance report worrying about affording prescription drugs---an even greater share than those with Medicare.[xxxiii] By extending the annual and other out-of-pocket cap established for Medicare to private insurance, millions of Americans will directly experience financial relief while tens of millions more are given peace of mind that drug costs will not bring financial ruin.

Reforming the Drug Supply Chain

While drug corporations abuse their monopoly power to set extraordinarily high prices, harmful business practices of Pharmacy Benefit Managers (PBMs) also drive-up pharmaceutical costs.

PBMs were created to manage health plan formularies and to negotiate lower prices – effectively, to serve as a countervailing power to Big Pharma. However, they have evolved to become adjuncts of health insurers and function as their own economic interest, manipulating markets, raising costs and imposing devastating harm on independent pharmacies, betraying their original price-lowering mission. The three largest PBMs, CVS Caremark, Express Scripts and OptumRx are now each integrated with a major health insurer. The top three PBMs manage nearly 80 percent of all prescriptions filled in the United States, and the largest 6 account for more than 90 percent.[xxxiv]

Consolidation and vertical integration allow PBMs to boost revenues at the expense of patients and health plans through tactics like pocketing portions of high rebates and discounts from manufacturers, and “spread pricing” wherein PBMs charge a plan more for a drug than they reimburse to a dispensing pharmacy.[xxxv] An FTC investigation found that PBMs boost revenues by steering patients towards their affiliated pharmacies and, at times, even excluding lower-cost generic or biosimilar competitors from formularies and preferring

expensive branded drugs with high rebates.[xxxvi] PBM preference for affiliated pharmacies has had a crushing impact on independent and community pharmacies that promote competition, serve low-population areas and strengthen community.[xxxvii] PBMs also generate billions of dollars in revenues by marking up drugs higher than their acquisition costs at their affiliated specialty pharmacies while costs for patients and employers and other health care plan sponsors increase.[xxxviii]

Policymakers have begun to address some abusive practices of PBMs, but significant reform is still needed. Investigations from the Federal Trade Commission (FTC) led to cases against the three largest PBMs, alleging that they drove up insulin costs for patients by creating a perverse incentive system that favored high-list price, high-rebate insulin over alternatives.[xxxix] In February, the FTC and ExpressScripts reached a settlement requiring ExpressScripts to adopt a number of reforms, including no longer preferring drugs with higher list prices over identical drugs with lower list prices, offering plans with out-of-pocket costs based on net prices, and delinking list prices from compensation in its standard plan.[xl] FTC reached a second settlement in July with Caremark Rx.[xli] The 2026 Consolidated Appropriations Act (CAA) required that for Medicare Part D, PBMs pass through all rebates to plan sponsors and for compensation to be provided based on a flat dollar amount, and not as a percentage of the price of a drug.[xlii] The CAA also required transparency measures between PBMs and plan sponsors in the private market, requiring disclosure of spread pricing, acquisition costs, rebates, and other information to help plan sponsors better evaluate their pharmacy benefits and costs, as well as by requiring full pass through of rebates in employer sponsored health plans.[xliii]

While these reforms will provide relief for patients, ultimately more fundamental reforms that address the underlying sources of power that facilitate the PBM abuses at the expense of patients – consolidation and vertical integration – will be needed. Through the Patients Before Monopolies Act,[xliv] Sens. Warren and Hawley have proposed to prohibit joint ownership of PBMs and pharmacies, and through the Break Up Big Medicine Act,[xlv] the senators have proposed to prohibit any parent company from owning a medical provider or management services organization and a PBM or insurer. Other pharmaceutical policy experts have proposed a public PBM model,[xlvi] built on the long history of the Department of Veterans Affairs successfully managing its own formulary through its Pharmacy Benefits Management Services.[xlvii]

Interim reforms can also help address a multitude of abuses presented by the PBM business model. Public Citizen urges policymakers to consider:

- Require Part D plans to include biosimilars with lower net prices on a formulary tier with costsharing terms more favorable to the patient than the tier on which its reference product is placed, to promote biosimilar competition and lower costs.
- Consider prohibiting PBM rebate arrangements that include any contingencies based on blocking or providing less favorable coverage to generics or biosimilars.
- Require patient coinsurance and costsharing to be calculated based on net price, so patients aren't harmed by PBM's preferring high-list price, high-rebate medicines. We agree that ideally such a policy should apply to the broadest array of drugs possible so more patients benefit from lower cost-sharing.
- Reimburse generic medicines in Medicare Part D on a cost-plus basis.
- Prohibit PBMs from owning private label drugs; at a minimum prohibit PBM-owned private labels unless they satisfy a cost-plus pricing standard.
- End the perverse incentive-inducing practice of reimbursing physician offices for Part B drugs based on sales price and instead move to a flat add-on payment.
- Calculate Part B reimbursement using a blended average sales price (ASP) that includes a biologic product and all biosimilars that reference it, to promote biosimilar competition.[xlviii]

<u>Supporting Biomedical Innovation</u>

Exploiting government-granted monopolies to charge captive payers and patients unfathomable prices is central to Big Pharma's business model. Prescription drug corporations aggressively exploit legal loopholes to strengthen and lengthen their patent monopolies. When drug corporations engage in legal tricks to strengthen and lengthen monopolies, it exposes our health system and patients to higher costs, limits access, and weakens incentives for companies to make true therapeutic advancements. Ultimately, this leads to increased health spending and poorer health outcomes for American patients.

In the short term, policymakers must rein in the worst of pharma's patent monopoly abuses that cost taxpayers and patients billions of dollars by preventing access to lower-cost alternatives through reforms including the ETHIC Act, the Drug Competition Enhancement Act, the Preserve Access to Affordable Generics and Biosimilars Act, and the Stop STALLING Act.

Over the medium- and long-term, policymakers should advance alternative research and development systems that delink[xlix] the financing of biomedical innovation from the end prices charged to patients and health systems, through prize funds, more upstream grant funding, and a greater public role in later stage development.

Patent Abuses Cost Billions

Patent evergreening occurs when drug corporations make trivial or obvious modifications to medications in order to lengthen exclusivity on brand name medicines. Public Citizen analysis of the first 10 drugs selected for the Medicare drug price negotiation program found that four of the 10 drugs subject to negotiation would likely have faced competition before negotiated prices went into effect were it not for evergreening tactics and patent abuses.[l] Pharmaceutical company tactics to extend their monopolies on these drugs included obtaining patents for minor or obvious variations including on (1) standard processes for screening compounds across the drug industry and (2) previously known information publicly available or disclosed in prior patents.[li] In other cases, companies used recently acquired patents that had nothing to do with producing a branded drug to block competing products and patented methods of screening patients to ensure the drug's safety and efficacy.[lii]

As a result, Medicare lost between $4.9 and $5.4 billion in savings that should have accrued from access to competing, lower-cost treatments.[liii] These lost savings are nearly as much as what Medicare was projected to save from negotiated prices going into effect on all of the selected drugs in the first year of the program ($6 billion).[liv] Evergreening practices were prevalent across the drugs selected for price negotiation in the first year of the program. Nine out of 10 drugs subject to negotiation show evidence of manufacturers engaging in blatant anticompetitive uses of patents to fend off generic or biosimilar competitors or evergreening abuses representing minor modifications or tweaks that unfairly lengthen monopoly protection on the drugs.[lv] Patent protection on the branded drugs could extend well into the 2030s and possibly 2040.[lvi]

Patent Thicketing

Drug companies build patent thickets by filing numerous patent applications with small changes that build on a previously filed parent patent. These continuation patents are obvious variants of previously issued patents. Drug firms even admit that these are obvious variants. However, companies can use a procedural tool, called a 'terminal disclaimer' to prevent the patent office from rejecting these applications as obvious variations of previously patented inventions. The disclaimers shorten the protection period of the continuation patent to that of the parent patent. Though these weak patents may not extend the patent life for the product, when companies secure multiple patents with interlocking claims covering the same invention, it becomes more difficult and costly for generics and biosimilars manufacturers to mount legal challenges and bring competition to market. While challenging a small number of patents may be manageable, requiring generic entrants to confront seven or eight patents imposes a substantially greater litigation burden.

For example, experts in pharmaceutical patent law and policy with Harvard Medical School's Program On Regulation, Therapeutics, And Law (PORTAL) noted that the patent thicket surrounding mega-blockbuster Humira, held by AbbVie, "consist[ed] of 105 patents connected by 436 terminal disclaimers."[lvii] The Humira patent thicket "helped AbbVie reach settlement agreements that delayed biosimilar market entry in the U.S. by five years compared to entry in Europe."[lviii] Were **ETHIC** in place, AbbVie would have only been able "to sue potential competitors to prevent market entry with a maximum of 24 patents instead of 105,"[lix] potentially decreasing the cost of entry for Humira biosimilars.

The ETHIC Act would help combat this monopoly abuse by allowing branded drug companies to assert only one patent per family of patents linked by terminal disclaimers in litigation. This would make it less onerous and costly for generics and biosimilars firms to challenge originator patents and bring price-lowering competition to market.

Product Hopping

Product hopping occurs when a drug corporation introduces a follow-on product with no significant therapeutic benefit over its predecessor and makes efforts to switch patients onto the new product to prevent potential generic or biosimilar competitors from gaining market share. This effectively prolongs monopoly pricing and profits for the drug corporation engaging in the abuse. Product hops of just five drugs have been estimated to cost the United States $4.7 billion annually.[lx]

As proposed through the Drug Competition Enhancement Act, enacting a prohibition on product hopping and empowering the Federal Trade Commission (FTC) to enforce this prohibition would stop drug corporations from taking advantage of these unfair monopoly extensions.

Pay-for-Delay Reverse Patent Settlements

Pay-for-delay deals, also known as reverse payment settlements, occur when a brand-name drug corporation provides something of value to a generic or biosimilar manufacturer in exchange for that manufacturer delaying the launch of a competing product. In 2013, the Supreme Court took a small step forward. Through the Actavis decision, the Supreme Court decided that while not presumptively illegal, pay-for-delay deals could be contested under antitrust principles,[lxi] but many types of pay-for-delay arrangements have persisted. Pay-for-delay deals post-Actavis decision are estimated to cost taxpayers and patients from $6.2 to $37.1 billion dollars per year.[lxii]

As proposed through the Preserving Access to Affordable Generics and Biosimilars Act, making pay-for-delay reverse patent settlement deals presumptively anticompetitive and

providing the FTC sufficient resources for aggressive enforcement would help put an end to this practice.

Citizen Petition Abuse

Citizen petition abuse occurs when a brand drug corporation formally raises with the Food and Drug Administration (FDA) safety concerns of a generic drug application to delay the launch of competition, and thereby inappropriately prolong the monopoly period for a brand-name drug. Drug corporations that file spurious petitions[lxiii] raise drug prices for consumers and taxpayers and hamper the FDA with the burden of reviewing sham filings.

As proposed through the Stop STALLING Act, empowering the FDA to dismiss sham petitions filed with the primary purpose of delaying competition and the FTC to pursue suits against such petitioners would support more timely generic competition and lower prices for patients and consumers.

Beyond these proposals, Congress should pass legislation that goes further to combat common pharmaceutical company monopoly abuses, including through reforming patent law so a secondary patent claiming a method of use for an indication which has already been disclosed or claimed in a primary patent relating to a product is obvious and, therefore, unpatentable,[lxiv] and preventing the pharmaceutical industry from unfairly extending exclusivity on drugs through crystalline/polymorph patents.[lxv]

Thank you for your commitment to ending prescription drug company profiteering and making medicines affordable for Americans.

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[i] Audrey Kearney, Alex Montero, Julian Montalvo III, Isabelle Valdes, Ashley Kirzinger, and Liz Hamel. "Public Views on Prescription Drug Costs: Regulation, Affordability and TrumpRx". KFF. March 13, 2026. https://www.kff.org/public-opinion/public-views-on-prescription-drug-costs-regulation-affordability-and-trumprx/

[ii] Center for Medicare and Medicaid Services. "NHE Projections: Prescription Drug Expenditures." Accessed July 30, 2026. https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/projected

[iii] Juliette Cubanski and Tricia Neuman. "Key Facts About Medicare Drug Price Negotiation." KFF. March 11, 2026. https://www.kff.org/medicare/key-facts-about-medicare-drug-price-negotiation/

[iv] Marinacci LX, Mein S, Rome BN, Wadhera RK. Cost-Related Medication Nonadherence After the Inflation Reduction Act. JAMA Intern Med. 2026;186(5):609–617. doi:10.1001/jamainternmed.2026.0012

[v] Congressional Budget Office. "Letter Re: Developments in CBO's Projections for Medicare Part D." July 29, 2026. https://www.cbo.gov/system/files/2026-07/62549-Medicare-Part-D.pdf

[vi] Wouters OJ, Kesselheim AS. Quantifying Research and Development Expenditures in the Drug Industry. JAMA Netw Open. 2024;7(6):e2415407. doi:10.1001/jamanetworkopen.2024.15407

[vii] Barber MJ, Gotham D, Bygrave H, Cepuch C. Estimated Sustainable Cost-Based Prices for Diabetes Medicines. JAMA Netw Open. 2024;7(3):e243474. doi:10.1001/jamanetworkopen.2024.3474

[viii] Sarah Karlin-Smith. "Why Medicare Must Negotiate Drug Price At Launch." Health Affairs Forefront. July 22, 2026. https://www.healthaffairs.org/content/forefront/why-medicare-must-negotiate-drug-prices-launch

[ix] Robert Langreth, "New Drug Prices Soar to $180,000 a Year on 20% Annual Inflation," *Bloomberg*, June 7, 2022, https://www.bloomberg.com/news/articles/2022-06-07/new-drug-prices-soar-to-180-000-a-year-on-20-annual-inflation

[x] Deena Beasley, "US prices for new drugs fell in 2025 as fewer costly gene therapies were launched, Reuters, June 25, 2026**,** https://www.reuters.com/business/healthcare-pharmaceuticals/us-prices-new-drugs-fell-2025-fewer-costly-gene-therapies-were-launched-2026-06-25/**;** Deena Beasley, "Prices for new US drugs doubled in 4 years as focus on rare disease grows," Reuters, May 22, 2025, https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-doubled-4-years-focus-rare-disease-grows-2025-05-22/

[xi] Center for Medicare. "Removal of Xeljanz; Xeljanz XR from the Selected Drug List Effective January 1, 2029." July 28, 2026. https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-5-july-27-31

[xii] David Lim. "Entresto, Stelara and Xarelto removed from Medicare negotiations", PoliticoPro. November 26, 2025. https://subscriber.politicopro.com/article/2025/11/entresto-stelara-and-xarelto-removed-from-medicare-negotiations-00670091

[xiii] U.S. Food & Drug Administration. "Designating an Orphan Product: Drugs and Biological Products", Accessed August 7, 2026. https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products

[xiv] Vogel M, Zhao O, Feldman WB, Chandra A, Kesselheim AS, Rome BN. Cost of Exempting Sole Orphan Drugs From Medicare Negotiation. *JAMA Intern Med*. 2024;184(1):63–69. doi:10.1001/jamainternmed.2023.6293

[xv] Chen, J. C., Madsen, C., & Kaltenboeck, A. (2026). The Economics Of Orphan Blockbuster Drug Development. *Health Affairs*, *45*(8), 838–845. https://doi.org/10.1377/hlthaff.2026.00209

[xvi] SYVERSEN, I.D., SCHULMAN, K., KESSELHEIM, A.S. and FELDMAN, W.B. (2024), A Comparative Analysis of International Drug Price Negotiation Frameworks: An Interview Study of Key Stakeholders. Milbank Quarterly., 102: 1004-1031. https://doi.org/10.1111/1468-0009.12714

[xvii] Congressional Record. "House Roll Call Vote 682, 116th Congress, 1st Session." December 12, 2019. https://www.congress.gov/votes/house/116-1/682

[xviii] Arnold Ventures and Fabrizio Ward. "New Poll Finds Americans Agree, Drug Prices are Too High and Congress Needs to Act." March 2025. https://www.arnoldventures.org/resources/national-targeted-cd-registered-voter-surveys

[xix] West Health Mosaic. "Negotiation Outcomes Calculator." Accessed July 31, 2026. https://westhealthmosaic.com/data-mosaics/negotiation-outcomes-calculator

[xx] Office of Assistant Secretary for Planning and Evaluation (ASPE), "Comparing Prescription Drugs in the U.S. and Other Countries: Prices and Availability," January 31, 2024, https://aspe.hhs.gov/reports/comparing-prescription-drugs

[xxi] Gabriel N, Martin K, Cousin EM, Li KH, Grueger J, Sullivan SD. Assessment of IPAY 2027 Medicare drug price negotiation maximum fair prices with prices in most-favored nation reference countries. J Manag Care Spec Pharm. 2026 May;32(5):530-539. doi: 10.18553/jmcp.2026.32.5.530. PMID: 42043921; PMCID: PMC13119479.

[xxii] Congressional Budget Office. "Letter Re: Developments in CBO's Projections for Medicare Part D." July 29, 2026. https://www.cbo.gov/system/files/2026-07/62549-Medicare-Part-D.pdf

[xxiii] Parasrampuria S, Murphy S. Comparing U.S. and International Market Size and Average Pricing for Prescription Drugs, 2017-2022: Issue Brief [Internet]. Washington (DC): Office of the Assistant Secretary for Planning and Evaluation (ASPE); 2024 Dec. Available from: https://www.ncbi.nlm.nih.gov/books/NBK611829/

[xxiv] Rodwin, M. A. (2021). Common Pharmaceutical Price and Cost Controls in the United Kingdom, France, and Germany: Lessons for the United States. *International Journal of Health Services*, *51*(3), 002073142199616. https://doi.org/10.1177/0020731421996168

[xxv] Arnold Ventures and Fabrizio Ward. "New Poll Finds Americans Agree, Drug Prices are Too High and Congress Needs to Act." March 2025. https://www.arnoldventures.org/resources/national-targeted-cd-registered-voter-surveys

[xxvi] Hwang TJ, Tibau A, Kesselheim AS, Vokinger KN. Implications of Medicare Negotiation and Most-Favored-Nation Pricing for Cancer Medicine Costs. JAMA Health Forum. 2026;7(5):e260509. doi:10.1001/jamahealthforum.2026.0509

[xxvii] United States Census Bureau. “Table 1: Number of People by Health Insurance Coverage Status and Type: 2023 to 2024.” https://www2.census.gov/programs-surveys/demo/tables/p60/288/table1.pdf
[xxviii] Matthew Rae, Krutika Amin, Cynthia Cox. “ACA’s maximum out-of-pocket limit is growing faster than wages”, Peterson-KFF Health Systems Tracker. July 20, 2022. https://www.healthsystemtracker.org/brief/aca-maximum-out-of-pocket-limit-is-growing-faster-than-wages/
[xxix] Center for Medicare and Medicaid Services. “NHE Tables: National Health Expenditures by Source of Funds and Type of Expenditures.” Accessed July 31, 2026. https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet
[xxx] Congressional Budget Office. “A Comparison of Brand-Name Drug Prices Among Selected Fedeal Programs”. February 2021. https://www.cbo.gov/publication/57007
[xxxi] Y. Ye, A. Pandey, M.C. Fitzpatrick, L. Potter-Schwartz, C. Bawden, B. Bilori, B.H. Singer, & A.P. Galvani, Estimating US savings on outpatient prescription pharmaceuticals from international reference pricing, Proc. Natl. Acad. Sci. U.S.A. 123 (2) e2520871122, https://doi.org/10.1073/pnas.2520871122 (2026).
[xxxii] Egilman, A. C., Kesselheim, A. S., & Rome, B. N. (2025). Share of sales subject to Medicare inflation rebates and price increases of top-selling drugs. *Health Services Research, 61*(1), e70012. https://doi.org/10.1111/1475-6773.70012
[xxxiii] Audrey Kearney, Julian Montalvo III, Ashley Kirzinger, and Liz Hamel. “Public Opinion on Prescription Drugs and Their Prices.” KFF. March 31, 2026.https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/
[xxxiv] Federal Trade Commission. “Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, Interim Staff Report”, July 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf
[xxxv] Elizabeth Y. McCuskey, “Federal PBM Reforms In Action And In Context”, February 26, 2026, https://www.healthaffairs.org/content/forefront/federal-pbm-reforms-action-and-context
[xxxvi] Federal Trade Commission. “Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, Interim Staff Report”, July 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf
[xxxvii] Reed Abelson and Rebecca Collins, The Powerful Companies Driving Local Drugstores Out of Business, New York Times, October 19, 2024, https://www.nytimes.com/2024/10/19/business/drugstores-closing-pbm-pharmacy.html
[xxxviii] Federal Trade Commission. “Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers, Second Interim Staff Report”, January 2025, https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf
[xxxix] Ed Silverman. “FTC settles lawsuit with Express Scripts over charges it manipulated insulin prices, impeded access” STAT News. February 4, 2026, https://www.statnews.com/pharmalot/2026/02/04/pbm-cigna-express-scripts-ftc-insulin-settlement-rebates/
[xl] Federal Trade Commission. “FTC Secures Landmark Settlement with Express Scripts to Lower Drug Costs for American Patients”, February 4, 2026, https://www.ftc.gov/news-events/news/press-releases/2026/02/ftc-secures-landmark-settlement-express-scripts-lower-drug-costs-american-patients
[xli] Federal Trade Commission. “FTC Secures Major Settlement with Caremark, Resolving Antitrust Case Against Second Drug Middleman”, July 14, 2026. https://www.ftc.gov/news-events/news/press-releases/2026/07/ftc-secures-major-settlement-caremark-resolving-antitrust-case-against-second-drug-middleman
[xlii] Elizabeth Y. McCuskey, “Federal PBM Reforms In Action And In Context”, February 26, 2026, https://www.healthaffairs.org/content/forefront/federal-pbm-reforms-action-and-context
[xliii] Ibid.
[xliv] Sen. Warren, “Warren, Hawley, Harshbarger, Auchincloss Renew Bipartisan Push to Rein In Pharmacy Benefit Managers (PBMs), Cut Drug Costs https://www.warren.senate.gov/news/press-releases/warren-hawley-harshbarger-auchincloss-renew-bipartisan-push-to-rein-in-pharmacy-benefit-managers-pbms-cut-drug-costs
[xlv] Sen. Warren, “The Break Up Big Medicine Act”, February 2026, https://www.warren.senate.gov/wp-content/uploads/media/doc/break_up_big_medicine_act_one-pager.pdf

[xlvi] Alejandro Molina & Reed Showalter, “Cutting Out the Middleman: A Public Option for Pharmacy Benefits”, June 2026, https://groundworkcollaborative.org/wp-content/uploads/2026/06/GW_Pharma_PBM-Proposal_FINAL.pdf
[xlvii] U.S. Department of Veterans Affairs, “Pharmacy Benefits Management Services”, Accessed June 25, 2026 https://www.pbm.va.gov/
[xlviii] Fiona Scott Morton, Zack Cooper. “Paying for Biologic PADs in Medicare Part B”, 1% Steps for Health Care Reform. Accessed August 14, 2026. https://onepercentsteps.com/policy-briefs/paying-for-biologic-pads-in-medicare-part-b/
[xlix] Knowledge Ecology International, “What Is Delinkage?”, Accessed June 1, 2026, https://delinkage.org/overview/
[l] Ibid.
[li] Ibid.
[lii] Ibid.
[liii] Ibid.
[liv] Ctrs. Medicare & Medicaid Servs., Fact Sheet: Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026 (Aug. 14, 2024), https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026
[lv] Jishian Ravinthiran, “Using the Inflation Reduction Act to Rein in Patenting & Evergreening Abuses,” Public Citizen, December 11, 2024, https://www.citizen.org/article/using-the-inflation-reduction-act-to-rein-in-patenting-evergreening-abuses/
[lvi] Ibid.
[lvii] Chao B, Whalen R, Kesselheim AS, Tu SS. Clearing Dense Drug-Patent Thickets. N Engl J Med 2024; 39(23): 2180-2182 https://www.nejm.org/doi/full/10.1056/NEJMp2412999
[lviii] “Combating Pharmaceutical Patent Thickets In The Trump Administration”, Health Affairs Forefront, August 13, 2025. DOI: 10.1377/forefront.20250811.410352
[lix] Chao B, Whalen R, Kesselheim AS, Tu SS. Clearing Dense Drug-Patent Thickets. N Engl J Med 2024; 39(23): 2180-2182 https://www.nejm.org/doi/full/10.1056/NEJMp2412999
[lx] Brill, Alex. “The Cost of Brand Drug Product Hopping”, Matrix Global Advisors, September 2020, https://getmga.com/wp-content/uploads/2022/04/CostofProductHoppingSept2020.pdf
[lxi] Feldman, R. (2022). The Price Tag of "Pay-for-Delay". *Science and Technology Law Review*, *23*(1), 1–49. https://doi.org/10.52214/stlr.v23i1.9389
[lxii] Ibid.
[lxiii] Michael A. Carrier, “Five Actions to Stop Citizen Petition Abuse”, Columbia Law Review Online, March 6, 2018, https://columbialawreview.org/content/five-actions-to-stop-citizen-petition-abuse-2/
[lxiv] I-MAK, Addressing Patent Thickets to Improve Competition and Lower Prescription Drug Price: A Blueprint for Reform 5 (2023).
[lxv] Jishian Ravinthiran, “Using the Inflation Reduction Act to Rein in Patenting & Evergreening Abuses,” Public Citizen, December 11, 2024, https://www.citizen.org/article/using-the-inflation-reduction-act-to-rein-in-patenting-evergreening-abuses/