Senate Finance Committee
Minority Staff

Request for Information: Commonsense Policy Options to Lower Drug Prices for Patients

June 16, 2026

Introduction & Executive Summary

On February 3, 2026, Ranking Member Wyden, along with Senators Cortez Masto, Welch, and Gallego, released a Dear Colleague to the Senate Democratic caucus outlining a three-pronged plan to build on Democrats' success under the *Inflation Reduction Act* to further lower prescription drug prices in the United States. Other Democratic Senators–including Senators Kelly, Baldwin, Hassan, Merkley, Van Hollen, Duckworth, and Blumenthal–have since joined this effort. Following the release of the Dear Colleague, Finance Committee minority staff and the involved Senate offices completed listening sessions with more than **70 external organizations** representing patients, consumers, and their advocates, academic researchers, think tanks, health insurers, and pharmaceutical companies to solicit initial ideas and feedback.

This Request for Information (RFI) builds upon the high-level plan outlined in the Dear Colleague and reflects our initial conversations during the listening sessions by providing more details about potential policy options that will: (1) reduce the prices pharmaceutical manufacturers charge for drugs; (2) directly lower patient out-of-pocket costs and address perverse incentives in the supply chain that keep prices high; and (3) bolster biopharmaceutical innovation for the future. A brief summary of the proposals contained in each section of the RFI can be found below.

Senate Democrats invite stakeholders and experts to provide feedback on the questions and proposals contained within this RFI. **Please submit written comments to drugs@finance.senate.gov no later than August 17, 2026.** Feedback will be used to help inform future legislative drafting.

Section I: Lowering Drug Prices

Senate Democrats are interested in proposals that will build on the success of the *Inflation Reduction Act* by continuing to lower the prices manufacturers charge for prescription drugs. Within Section I of this RFI, we request feedback on the following specific policy options and questions:

- Expanding Medicare drug price negotiations, including by factoring international prices into Medicare drug price negotiation and ultimately finding a pathway to lower drug prices in the commercial market;
- Allowing the Health and Human Services Secretary (Secretary) to negotiate more drugs each year;
- Allowing the Secretary to negotiate prices earlier in drug product lifecycles and when such negotiations should occur on small molecule and biologic drugs;
- Developing incentives to support biosimilars in the event biologic medicines are subject to negotiation earlier in their lifecycle;
- Eliminating the blockbuster drug bailout included in the 2025 Republican reconciliation package and replacing it with the *No Big Blockbuster Bailouts Act* (S. 3019);
- Enhancing Medicare inflation rebates through re-basing, incorporating Medicare Advantage units for Part B drugs, and/or extending such rebates to the commercial market; and

- Developing a subscription model to help facilitate access and lower pricing on certain drugs utilized by broad populations, including GLP-1s.

Section II: Enhancing Prescription Drug Affordability

Senate Democrats are interested in proposals that will lower out-of-pocket costs for patients. Within Section II of this RFI, we request feedback on the following specific policy options and questions:

- Applying out-of-pocket caps to more chronic care drugs in Medicare beyond insulin;
- Determining whether cost-sharing under the deductible and when coinsurance applies should be based on net drug prices or if there are other mechanisms for holding Pharmaceutical Benefit Managers (PBMs) and plans accountable when they prefer high-list price products over lowered-priced alternatives;
- Moving to a cost-plus/NADAC-based reimbursement model for generic medicine ingredient costs;
- Expanding eligibility for Part D Low-Income Subsidies (LIS);
- Containing Part D premiums;
- Addressing inflated prices on PBM-owned private label drugs;
- Prohibiting or putting guardrails around PBMs' ability to limit direct contracting between manufacturers, health plans, and other entities in Medicare Part D and other markets;
- Increasing PBM accountability to contain pharmacy trend and deliver lower net effective drug costs;
- Addressing potential Medicare program abuses that occur through vertical integration;
- Helping pharmacies become less reliant on drug margin as a form of compensation by ensuring reasonable dispensing fees in Medicare Part D;
- Building on Part D delinking by addressing additional forms of price-linked compensation in the supply chain, including physician add-on payments in Part B; and
- Holding health insurance plans and PBMs accountable for inappropriate pharmacy rejections in Part D.

Section III: Bolstering Biopharmaceutical Innovation in the United States

Senate Democrats are interested in proposals that will bolster and invest in biopharmaceutical innovation by enhancing research and development (R&D) investments and incentives in areas of unmet need, bolstering domestic clinical trials, and recruiting and maintaining scientific talent in the United States. Within Section III of this RFI, we request feedback on the following specific policy options and questions:

- Creating new incentives for universities and academic medical centers to engage in basic research that could lead to new cures and treatments;
- Creating new funding streams for basic and translational biomedical research;
- Developing new incentives for nonprofit and private sector entities to develop or use existing therapeutic accelerators that work to translate promising basic research discoveries into commercialized medicines;
- Targeting new incentives for research at various stages of the drug development process in areas of unmet clinical need or high-risk science;
- Providing new incentives for small biotechnology companies that are working to develop drugs in high-risk areas and meet certain standards;

- Increasing clinical trial participation in the United States and making the clinical trial process more efficient and affordable;
- Developing new incentives that would help cultivate, recruit and retain scientific talent in the biomedical field in the United States; and
- Replicating and adapting provisions of the *Inflation Reduction Act* or *CHIPS and Science Act* to address similar issues related to global competitiveness in the biopharmaceutical space.

Section I: Lowering Drug Prices

Pharmaceutical companies continue to charge excessively high prices for prescription drugs in the United States. In 2025 alone, IQVIA projects the United States spent $606 billion on prescription drugs.[1] Drug launch prices in the United States also appear to be rising.[2] Meanwhile, the pharmaceutical industry has enjoyed significantly higher profit margins than other parts of the health care sector, with net profit margins for brand pharmaceutical companies often exceeding 20 percent.[3]

Senate Democrats stand ready to take meaningful action to further lower prescription drug prices. We request feedback on policy options that would: (1) enhance Medicare's ability to negotiate lower drug prices with manufacturers; (2) bolster penalties when manufacturers engage in price gouging; and (3) use novel approaches to lower prices on drugs used by broad segments of the United States population and to address launch prices.

While the following proposals focus primarily on lowering drug prices in Medicare, Senate Democrats recognize that policy solutions for the commercial and employer markets are also badly needed. As Democrats engage in broader health policy discussions about how to rebuild the health care system and restore coverage for millions of Americans who will lose their insurance because of Republicans' 2025 reconciliation law (H.R.1),[4] we will also consider how best to lower drug prices in markets beyond Medicare. These solutions may include extending Medicare-negotiated pricing to other markets or developing new mechanisms for other markets to negotiate lower drug prices.

I. Bolstering Medicare's Ability to Negotiate Lower Drug Prices

In 2022, Democrats—without a single Republican vote—took *meaningful* action to lower drug prices by giving Medicare the long overdue authority to negotiate prescription drug prices. This year, lower Medicare-negotiated prices for the first ten drugs selected for negotiation took effect, saving an estimated $6 billion for taxpayers and $1.5 billion in out-of-pocket costs for seniors and people with disabilities on Medicare.[5] These ten medications are taken by more than 8 million Medicare enrollees and treat conditions like diabetes, cancer, blood clots, and heart disease. The negotiated prices on the second round of drugs, which go into effect in 2027, will

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[1] "U.S. Medicine Use Trends 2026," The IQVIA Institute, April 28, 2026, https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/us-medicine-use-trends-2026.

[2] 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/

[3] Fred D. Ledley et al., "Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies," *JAMA* 323, no. 9 (2020): 834–843, https://doi.org/10.1001/jama.2020.0442

[4] *An act to provide for reconciliation pursuant to title II of H. Con. Res. 14,* Public Law 119-21, https://www.congress.gov/bill/119th-congress/house-bill/1/text.

[5] "Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026," Centers for Medicare & Medicaid Services, August 15, 2024, https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026.

expand on this success, saving $12 billion for taxpayers and $685 million in out-of-pocket costs for Medicare beneficiaries.[6]

Voters of all political affiliations are strongly supportive of expanding and building upon Medicare drug price negotiation. For example, 86 percent of voters in the 2024 election support preserving or expanding Medicare's ability to negotiate drug prices, including 81 percent of Republican voters.[7] Approximately 86 percent of Trump voters believe it is important for Medicare to negotiate drug prices. In fact, more than two-thirds of voters, including 66 percent of Trump voters, want to *expand* Medicare negotiation to *all* drugs.[8]

Democrats stand ready to answer this call. Senate Democrats thus request feedback on the following concepts and proposals related to expanding Medicare drug price negotiation.

Factoring International Pricing into Negotiation

The United States pays the highest prices in the world for prescription drugs. For every dollar spent on prescription drugs in other Organisation for Economic Co-operation and Development (OECD) countries, consumers in the United States pay $2.78. Gross brand drug prices in the United States are approximately 422 percent higher than other OECD nations, while net brand drug prices in the United States are estimated to be approximately 322 percent higher.[9] In 2022, the pharmaceutical industry sold approximately $617.2 billion worth of prescription drugs in the United States, compared to $371.7 billion in all other OECD countries combined. In other words, the United States has 62.4 percent of pharmaceutical sales among OECD countries, despite having only 23.8 percent of volume.[10]

The disparity between what the United States and countries abroad pay for prescription drugs is deeply unfair to American patients and their families. Trump has tried to capitalize on Americans' frustration by claiming that he is bringing drug prices in the United States down to international levels. None of his efforts, however, have delivered results. In fact, most appear to be intentionally unserious. For example:

- During his first term, Trump campaigned on promises to significantly lower American drug prices compared to international levels. Nearly all of his efforts failed, however, including a rulemaking that would have capped the amount Medicare Part B paid for certain drugs at international levels.[11]

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[6] "New Lower Drug Prices Under the Medicare Drug Price Negotiation Program," Centers for Medicare & Medicaid Services, November 2025, https://www.cms.gov/files/document/infographic-negotiated-prices-ipay-2027.pdf

[7] Geoff Garin, "Democrats Have a Winning Hand to Play on Healthcare," Hart Research, January 24, 2025, https://www.protectourcare.org/wp-content/uploads/2025/02/Protect-Our-Care-Polling-Memo-1-24-2025.pdf

[8] "National & Targeted CD Registered Voter Surveys," Arnold Ventures, April 22, 2025, https://www.arnoldventures.org/resources/national-targeted-cd-registered-voter-surveys

[9] "International Prescription Drug Price Comparisons: Estimates Using 2022 Data," Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services, February 2024, https://aspe.hhs.gov/sites/default/files/documents/8e057b0a094e6f9b9d01171fce6698f4/international-price-comparisons.pdf

[10] ASPE, "International Prescription Drug Price Comparisons."

[11] Brendan Pierson, "Federal judge blocks Trump administration drug pricing rule," *Reuters*, December 23, 2020, https://www.reuters.com/article/business/healthcare-pharmaceuticals/federal-judge-blocks-trump-administration-drug-pricing-rule-idUSKBN28X2IF/

- During his second term, Trump has instead pursued voluntary agreements with pharmaceutical manufacturers that appear to be mostly smoke and mirrors. These agreements purportedly impose Most Favored Nation (MFN) pricing in Medicaid and require launch prices to reflect MFN pricing, among other things. Details about the agreements, including their actual terms, however, remain shrouded in secrecy. Senate Democrats introduced legislation to require the Trump Administration to release the agreements (the *Drug Deal Disclosure Act*, S. 4355),[12] and issued a report outlining many reasons why the American public should be extremely skeptical that these agreements will lower their drug costs.[13]
- Trump has also issued two proposed rules during his second term that purport to bring the prices of certain drugs down to MFN levels in Medicare Parts B and D. However, manufacturers are openly telling their shareholders and the press that they will be exempt from these rulemakings as long as they enter into sham drug pricing agreements with Trump.[14] Democrats have reached out to the Administration seeking clarity on the extent of the exemptions, but have not received a response as of the date of this writing.[15]

The industry's long-held posture against international reference pricing also appears to be softening. Despite lobbying aggressively against all forms of "price controls" for decades, the world's largest brand pharmaceutical companies have now embraced the concept of international reference pricing in Medicaid and with respect to launch prices. Seventeen of the largest manufacturers have entered into voluntary agreements to this effect with the Trump Administration, many of whom sent their CEOs to stand with Trump in the Oval Office to tout these agreements to the press. At the same time, many of these companies are also suing the federal government in hopes of tearing down Democrats' landmark Medicare drug price negotiation law, which meaningfully lowers drug prices for the American people. These inconsistencies in positioning have not gone unnoticed by Senate Democrats.

Notably, to date, all attempts by pharmaceutical manufacturers to use the courts to tear down Medicare drug price negotiations, including challenges before the United States Supreme Court, have altogether failed. While Trump touts sweetheart deals with drug companies, Democrats delivered durable policy change to begin lowering Americans' prescription drug prices. Democrats recognize more must be done to lower prices, and will not sell false promises to the public.

We invite feedback on how best to incorporate international pricing into the Medicare drug price negotiation framework. Incorporating consideration of international pricing into Medicare drug price negotiation would lower drug costs for seniors and people with disabilities and could save taxpayers billions. Currently, the Secretary does not consider international pricing as part of the negotiation process. Rather, to inform offers made to manufacturers through

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[12] Drug Deal Disclosure Act, S. 4355, 119th Cong. (2026), https://www.congress.gov/bill/119th-congress/senate-bill/4355
[13] "Trump's Big Pharma Giveaway," United States Senate Finance Committee, April 21, 2026, https://www.finance.senate.gov/imo/media/doc/drug_deal_disclosure_act_accompanying_report.pdf
[14] Max Bayer, "Drugmakers with White House MFN deals claim exemption from proposed Medicare pricing tests," *Endpoints News*, December 24, 2025, https://endpoints.news/drugmakers-with-white-house-pricing-deals-may-skirt-new-medicare-demos/
[15] Ranking Members Ron Wyden, Frank Pallone, Jr., and Richard E. Neal to Secretary Robert F. Kennedy, Jr., March 5, 2026, https://democrats-waysandmeans.house.gov/sites/evo-subsites/democrats-waysandmeans.house.gov/files/evo-media-document/hhs.2026.03.05.letter-re-globe-and-guard-models.pdf

Medicare negotiation, the Secretary considers manufacturer-specific data (e.g., research and development costs, unit costs of production and distribution, federal financial support for discovery and development, patents and exclusivities, and domestic sales and market data) as well as evidence about alternative treatments.

At minimum, the Secretary should be authorized to consider international drug pricing data as a factor in the negotiation process. Additionally, the ceiling for Medicare-negotiated prices could be lowered in various ways based on international pricing. Currently, the ceiling price for maximum fair prices (MFPs) is the lower of:

- Net prices for Part D drugs or the Average Sales Price (ASP) for Part B drugs; or
- The applicable percentage of the drug's non-FAMP (the average price paid by wholesalers for drugs that does not account for prices paid by the federal government).

There are several approaches policymakers could take to incorporating international pricing into the ceiling price. First, a third prong based on international prices could be added to the current ceiling price calculation. Thus, the ceiling price would be the lowest of the current two prices or a percentage of an international reference price. Under the original version of the Medicare drug price negotiation legislation in the House (H.R. 3),[16] the ceiling for negotiated prices was set at 120 percent of an Average International Market Price ("AIM Price"). Alternatively, policymakers could also lower ceiling prices based on the current two-prong calculation by a set percentage when the existing ceiling price is substantially higher than an international reference price. This approach would penalize manufacturers for overcharging the United States without directly importing foreign prices.

Determining which countries' prices will be considered in the market basket is important. Previous policies have included different countries in their market baskets. For example, H.R. 3's AIM Price was based on drug prices in Australia, Canada, France, Germany, Japan, and the U.K. The first Trump Administration's MFN proposal considered prices from all OECD countries with per capita GDP of at least 60 percent of the U.S. per capita GDP, which could include 15 countries or more. The current Trump Administration is purportedly calculating most-favored nation pricing based on prices from Canada, Denmark, France, Germany, Italy, Japan, Switzerland, and the U.K.

Under any version of an international reference price proposal, the pricing data submitted to the federal government may be inflated compared to the true net prices other countries pay. For example, more countries abroad are beginning to use confidential rebates to hide their true net prices. In January 2025, Germany passed new laws making certain rebates confidential so it could receive deeper discounts that would not be reflected in other countries' international reference pricing policies.[17] Manufacturers would likely be prohibited from turning data about confidential rebates over to the United States government, pursuant to the terms of agreements with those countries. Proposals with shorter lists of countries, however, could potentially be easier to game.

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[16] Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/house-bill/3

[17] Brendan Melck, "All change in Germany – confidential pricing in, IRP out," *Pharmaceutical Technology*, January 31, 2025, https://www.pharmaceutical-technology.com/analyst-comment/all-change-germany-confidential-pricing-irp/

Lastly, incorporating international prices into Medicare drug price negotiation may have an impact on future biopharmaceutical innovation, though the magnitude of the impact and what types of products are most likely to be affected may be difficult to predict. The United States is by far the largest and most important market in the world for prescription drugs. As noted above, in 2022, the pharmaceutical industry sold approximately $617.2 billion worth of prescription drugs in the United States, compared to $371.7 billion in all other OECD countries combined. In other words, the United States has 62.4 percent of pharmaceutical sales among OECD countries, despite having only 23.8 percent of volume.[18] Thus, drug pricing policies in the United States are likely to have a disproportionate impact on the industry relative to similar policies abroad. While industry profit margins tend to be high,[19] the extent to which drug price reductions could be absorbed without adversely impacting pipelines with respect to clinically meaningful innovation is not known and would likely be contingent upon the policy specifics.

Negotiating Lower Prices on More Drugs

Under the *Inflation Reduction Act* (IRA), the Secretary is required to select a set number of drugs each year for Medicare drug price negotiation. Specifically, the Secretary must select 10 negotiation-eligible drugs for 2026, 15 negotiation-eligible drugs in 2027 and 2028, and 20 negotiation-eligible drugs in 2029 and beyond. Drugs must meet various criteria to be considered "qualified single source drugs" (QSSD) eligible for negotiation, such as being on the market for a certain period of time and incurring at least $200 million in annual Medicare spend in a single year, among other factors.

As noted above, voters of all political affiliations strongly support allowing Medicare to negotiate prices for more drugs. Senate Democrats are considering requiring the Secretary to select a minimum number of drugs per year for negotiation and allowing the Secretary to negotiate additional QSSDs beyond the minimum amount. This approach would allow the Secretary to negotiate more drugs faster, while still being mindful of potential administrative limitations on the number of drugs CMS has capacity to negotiate each year. **We request expert and stakeholder feedback on this concept and other approaches to allowing the Secretary to negotiate more drugs annually.**

Delivering Lower Negotiated Drug Prices to Patients Faster

Some policymakers, experts, and advocates argue that the Secretary should be empowered to negotiate drugs earlier in their product lifecycle. Doing so would enable patients to access lower pricing on prescription drugs faster. Under current law, to be considered a QSSD eligible for negotiation, small-molecule drugs must be on the market at least seven years, and biologic drugs must be on the market for at least 11 years. "Maximum fair prices" (MFPs) negotiated by the Secretary do not go into effect until two years after negotiation. So effectively, MFPs go into effect nine years and 13 years after FDA approval for small-molecule and biologic drugs, respectively. These timelines theoretically give companies time to recoup their investments in

[18] ASPE, "International Prescription Drug Price Comparisons."
[19] "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals," United States Government Accountability Office, November 17, 2017, https://www.gao.gov/products/gao-18-40

developing drugs, which helps preserve incentives for manufacturers to invest in research and development.

Since the IRA's enactment, the pharmaceutical industry has aggressively lobbied to create parity between small-molecule and biologic time on the market prior to negotiation. The industry argues that the disparity between nine years (for small molecule drugs) and 13 years (for biologics) is a "pill penalty" that creates a disincentive to invest in small molecule drug development. They are therefore advocating that Medicare refrain from negotiating the price of small molecule drugs until they have been on the market for 13 years. Since small molecule drugs typically get generic competition after 12.5 to 13.5 years,[20] this proposal would severely hamper Medicare's ability to negotiate prices for small molecule drugs *altogether*. Furthermore, the extent to which the IRA is reducing investments in small molecule drug development is unclear, and some studies find that investments in R&D increased following the IRA's enactment.[21] Many pharmaceutical companies continue to make acquisitions in the small molecule space, with investments growing from $23 billion in 2024 to $38 billion in 2025.[22]

Alternatively, some experts have suggested establishing parity between biologics and small molecule drugs at the nine-year threshold since biologics tend to yield higher returns on investment on similar timelines to small molecule drugs. While biologics tend to be more expensive to develop than most small molecule drugs, they also tend to generate significantly more revenue, with biologics earning an average of $3.7 billion over the life of the product compared to $2 billion for small molecule drugs. An analysis by the Brookings Institute projects that, among nine biologic drugs potentially likely to be selected for negotiation in the next few years, all nine are projected to achieve over $3 billion in net retained sales over their first eight years on market.[23]

Other existing proposals would negotiate drug prices (or impose other forms of drug price reductions) on even faster timelines. For example, the *SMART Prices Act* (S. 1836), led by Senator Klobuchar (D-MN) would allow Medicare to select drugs for negotiation after three years on market for both small-molecule and biologic drugs, with maximum fair prices taking effect after five years. The first Trump Administration's MFN proposal would have reimbursed Part B drugs at significantly lower MFN prices regardless of how many years a drug had been on the market. The second Trump Administration's GLOBE and GUARD models also do not specify a minimum amount of time a product must be on market before price reductions take

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[20] Henry Grabowski et al., "Updated trends in US brand-name and generic drug competition," *Journal of Medical Economics* 19, no. 9 (2016): 836-844, https://doi.org/10.1080/13696998.2016.1176578; Reed F. Beall et al., "A Method for Approximating Future Entry of Generic Drugs," *Value in Health* 21 (2018): 1382-1389, https://doi.org/10.1016/j.jval.2018.04.1827; Reed F. Beall et al., "Comparing Onset of Biosimilar Versus Generic Competition in the United States," *Clinical Pharmacology & Therapeutics* 108, no. 6 (2020): 1308-1314, https://doi.org/10.1002/cpt.1981; Olivier Wouters et al., "Differential Legal Protections for Biologics vs Small-Molecule Drugs in the US," *JAMA* 332, no. 24 (2024): 2101-2108, https://pubmed.ncbi.nlm.nih.gov/39585667/

[21] Henry Dao and Fred D. Ledley, "Sustaining pharmaceutical innovation after the Inflation Reduction Act: trends in R&D spending, equity investment, and business development," *Drug Discovery Today* 30, no. 7 (2025), https://doi.org/10.1016/j.drudis.2025.104394

[22] Richard G. Frank, "What Earnings Calls And SEC Filings Reveal About The State Of Pharma," *Health Affairs Forefront* (2026), https://doi.org/10.1377/forefront.20260330.665473

[23] Richard G. Frank and Yihan Shi, "Cumulative net earnings of drugs selected or likely to be selected for negotiation," *Brookings*, May 13, 2025, https://www.brookings.edu/articles/cumulative-net-earnings-of-drugs-selected-or-likely-to-be-selected-for-negotiation/

effect. Rather, price reductions would apply as soon as the drugs meet other criteria for the demonstrations, such as when they reach certain Medicare spending thresholds. In other countries, drug prices are typically negotiated early in drug product lifecycles. Many countries require drug price negotiation or impose price setting as a condition of market access and reimbursement (e.g., the U.K. and France). Other countries take different approaches, but still negotiate much earlier than the United States. For example, Germany will allow a product to launch for six months prior to negotiating reimbursement.

Senate Democrats are interested in delivering lower Medicare-negotiated drug prices to patients faster by allowing the Secretary to negotiate prices earlier in drug product lifecycles. **We seek feedback on different timeframes, including input on affordability and innovation considerations**.

Importantly, we request feedback on how accelerating timelines for Medicare negotiation might influence investment decisions by generic and biosimilar manufacturers. While small-molecule generics can often be developed for several million dollars, biosimilars are significantly more expensive to develop than generics, often costing several hundred million dollars.[24] Furthermore, biosimilars face numerous barriers to market entry (e.g., more patents and longer market exclusivity on reference biologics), which could impede their ability to launch prior to Medicare-negotiated pricing taking effect. Currently, only around 10 percent of brand biologic medicines expected to lose patent protection in the next decade currently have a biosimilar in development.[25]

To help mitigate unpredictability in the market for biosimilar manufacturers, accelerating timelines for Medicare negotiation should potentially be coupled with new incentives for biosimilar development and coverage. **Senate Democrats invite experts and stakeholders to submit policy ideas that would help boost the biosimilar market.** We are specifically interested in feedback and ideas related to the following concepts:

- New incentives to boost development and help accelerate biosimilar market entry for brand products that are likely to be selected for negotiation;
- Formulary placement policies in Medicare Part D that incent favorable coverage for low list price biosimilars;
- Modifications to mandatory discounts owed by biosimilar manufacturers under government programs (e.g., Part D Manufacturer Discount Program, Medicaid Drug Rebate Program, 340B Program);
- Prompt issuance of biosimilar J-codes by CMS; and
- Program integrity policies that would reduce anticompetitive behavior by brand manufacturers and middlemen in the supply chain, such as policies addressing rebate bundling strategies in both Medicare Parts B and D.

[24] Miriam Fontanillo et al., "Three imperatives for R&D in biosimilars," McKinsey & Company, August 19, 2022, https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars

[25] "FDA Moves to Accelerate Biosimilar Development and Lower Drug Costs," United States Food & Drug Administration, October 29, 2025, https://www.fda.gov/news-events/press-announcements/fda-moves-accelerate-biosimilar-development-and-lower-drug-costs

Eliminating Blockbuster Bailouts

Despite overwhelming support for Medicare drug price negotiation from voters across the political spectrum, Republicans included policies in H.R. 1 that exempted more drugs from negotiation, providing an $8.8 billion windfall to pharmaceutical companies on some of the world's biggest blockbuster drugs. Some of these drugs include Keytruda, the literal top-selling drug in the world in 2025, as well as Darzalex and Opdivo, which were the sixth and eleventh best-selling drugs in the world in 2025.[26] Darzalex, which will now be completely exempt from negotiation, has projected 2024 Medicare expenditures of over $6 billion.[27] These are far from the only three drugs that will be bailed out of negotiation as a result of this harmful Republican policy.[28]

Specifically, Republicans exempted all drugs from Medicare negotiation that exclusively have rare disease ("orphan") indications and delayed Medicare's ability to negotiate drugs that came to market with an orphan indication first and later got approved for a non-orphan indication. As a result, seniors and people with disabilities who have cancer or rare diseases are going to be forced to pay more for their prescription drugs. For example, even a 22 percent discount off of Keytruda's net price would generate annual savings of around $3,300 on cost-sharing liability for Medicare beneficiaries who use that drug.[29]

Senate Democrats recognize that orphan drug development presents unique financial challenges for manufacturers due to the small size of rare disease patient populations. Congress has previously enacted laws to help create and protect incentives for orphan drug development. Pursuant to those laws, orphan drugs are already eligible for extended FDA market exclusivity, special R&D tax incentives, waivers from FDA user fees, and more. Thus, orphan drugs already enjoy a number of special benefits in addition to Republicans' new exclusion from Medicare negotiation, which will stick patients and taxpayers with higher prices.

Patients with cancer and rare diseases should not have to pay sky-high prices for their medicines just because they need to take a drug that is or was once an orphan drug. A better approach would be to ensure that Medicare can still negotiate the prices of orphan drugs that have high levels of Medicare spending and are likely to be considered blockbuster products. Last year, Ranking Member Wyden co-led the *No Big Blockbuster Bailouts Act* (S. 3019) with Senators Welch (D-VT) and Cortez Masto (D-NV). This legislation would empower Medicare to still negotiate prices once a drug hits blockbuster status by repealing the Republican bailout and replacing it with a higher spending threshold ($400 million in annual Medicare spending) for

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[26] "Revised Estimate of Changes Under the 2025 Reconciliation Act for Exemptions From Medicare Price Negotiations for Orphan Drugs," Congressional Budget Office, October 20, 2025, https://www.cbo.gov/publication/61818; Tristan Manalac, "Keytruda Hangs On to Best Seller Crown as GLP-1s Gain Ground," *BioSpace*, March 4, 2026, https://www.biospace.com/business/keytruda-hangs-on-to-best-seller-crown-as-glp-1s-gain-ground

[27] Kristi Martin et al., "Blockbusters And Loopholes: Expanding Exemptions In Medicare Drug Price Negotiations," *Health Affairs Forefront*, August 29, 2025, https://doi.org/10.1377/forefront.20250827.726892

[28] Martin et al., "Blockbusters and Loopholes."

[29] Juliette Cubanski and Tricia Neuman, "People with Medicare Will Face Higher Costs for Some Orphan Drugs Due to Changes in the New Tax and Budget Law," *KFF*, October 20, 2025, https://www.kff.org/medicare/people-with-medicare-will-face-higher-costs-for-some-orphan-drugs-due-to-changes-in-the-new-tax-and-budget-law/

orphan-only drugs to become eligible for negotiation. **Senate Democrats are committed to reversing Republicans' orphan bailout and invite feedback on this replacement framework.**

II. Enhancing Manufacturer Accountability for Price Gouging

Congress should also take additional steps to ensure pharmaceutical companies are held accountable when they price gouge. In most other countries, drug price increases following the launch of a product are often tightly controlled or limited. The United States, however, has a long history of more aggressive list price increases by manufacturers. According to a 2023 analysis, the top 25 brand drugs in Part D spending have tripled in price since launch, accounting for $81 billion in Medicare spending in 2021.[30]

In 2022, Democrats worked to address this problem by imposing price gouging penalties in Medicare on pharmaceutical companies that increase drug prices at a rate faster than inflation. The Congressional Budget Office (CBO) estimated these provisions would save taxpayers over $63 billion over a ten-year budget window.[31] While these provisions are still in the early stages of implementation, a Finance Committee minority analysis found the Medicare inflation rebates are already slowing drug price growth and leading to savings.[32] The median percentage list price increase on brand drugs has steadily decreased from five percent in 2023 to four percent in both 2025 and 2026.[33] Nevertheless, manufacturers continue to increase their prices.

Senate Democrats are interested in bolstering Medicare's price gouging penalties. We are specifically interested in hearing from stakeholders about the following policy options:

- Re-Basing: Medicare's price gouging penalties currently calculate penalties for manufacturers from a baseline of 2021 drug prices. Manufacturers, however, should arguably be held accountable for arbitrary price increases that occurred prior to 2021, which cost patients and taxpayers billions of dollars. **Senate Democrats therefore request feedback on whether the Medicare price gouging penalties should be "re-based" to an earlier year, and what such earlier year should be.**
- Extension to MA Units: The Part B Medicare price gouging penalties currently do not apply to units of drugs administered under the Medicare Advantage (MA) program, which means manufacturers do not pay penalties on Part B drugs administered under MA, even where they took a price increase.[34] **Senate Democrats request stakeholder feedback on how to extend the Part B penalties to MA units.**
- Extension to Commercial Units: This policy would extend the Part B and Part D inflation rebates to units of drug sold in the commercial market, which is the approach taken under

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[30] Dena Bunis, "Top 25 Medicare Drugs Have Tripled in Price Since Coming on Market," *AARP*, August 23, 2023, https://www.aarp.org/advocacy/medicare-drug-prices-triple-2023/

[31] Juliette Cubanski et al., "Explaining the Prescription Drug Provisions in the Inflation Reduction Act," *KFF*, January 24, 2023, https://www.kff.org/medicare/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/

[32] "Wyden Highlights Savings for Seniors Thanks to IRA Price-Gouging Penalties," United States Senate Finance Committee, August 27, 2024, https://www.finance.senate.gov/chairmans-news/wyden-highlights-savings-for-seniors-thanks-to-ira-price-gouging-penalties

[33] "This is the Way … to Analyze Changes in Brand Drug List Prices," 46brooklyn, last accessed May, 2026, https://www.46brooklyn.com/branddrug-boxscore

[34] Christen Linke Young, "The inflation rebate for Medicare Part B-covered drugs should apply to Medicare Advantage," *Brookings,* May 14, 2025, https://www.brookings.edu/articles/the-inflation-rebate-for-medicare-part-b-covered-drugs-should-apply-to-medicare-advantage/

the *Lower Drug Costs for Families Act* (S. 1186), led by Senator Cortez Masto (D-NV). This change would expand the applicability of the rebate penalties and result in most of the prescription drug market in the United States being subject to inflation rebate penalties, since they also exist in Medicaid. **Senate Democrats request feedback on this proposal.**

III. Potential New Payment Models for Prescription Drugs

Senate Democrats are also interested in exploring novel pricing and payment models for prescription drugs that could further enhance affordability and patient access. Specifically, we are interested in payment models that could help increase access to medicines taken by broad populations (e.g., GLP-1s) as well as payment models that would address excessively high launch prices.

Subscription Models

Novel approaches to drug payment may help contain costs for certain prescription drugs that are likely to be used by large portions of the population and could otherwise be budget-busting for governments and other payers. One such example is glucagon-like peptide-1 receptor agonists (GLP-1s), which are indicated to treat obesity, diabetes, cardiovascular disease, and other diseases and conditions. Coverage of GLP-1s for obesity is patchy across multiple health insurance markets in the United States due to high anticipated utilization and costs associated with these therapies, payer concerns about adverse selection, and other factors. For example:

- Medicare Part D statutorily prohibits coverage of "weight loss drugs."[35]
- State Medicaid programs have the option of covering GLP-1s for obesity, but most states choose not to. Only 13 state Medicaid programs cover GLP-1s for obesity, often with prior authorization requirements. That number is down from 16 states since Trump signed nearly $1 trillion in Medicaid cuts into law as part of H.R. 1.[36]
- Coverage of GLP-1s for obesity in the commercial and employer markets also remains low, and where it does exist, there are often significant prior authorization and utilization management requirements. For example, an analysis of 2024 plan data found that only one percent of *Affordable Care Act* (ACA) Marketplace plans covered GLP-1s for obesity.[37] In 2025, 19 percent of employers offered coverage of GLP-1s for obesity, including 43 percent of large employers with over 5,000 employees.[38] Denial rates are high, however, even where the drugs are covered. For example, IQVIA estimated insurers denied 62 percent of GLP-1 prescriptions for obesity in 2024.[39]

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[35] "How Would Authorizing Medicare to Cover Anti-Obesity Medications Affect the Federal Budget?," Congressional Budget Office, October 8, 2024, https://www.cbo.gov/publication/60816#:~:text=The%20CBO%20estimates%20that%20the%20policy%20would:,federal%20costs%20by%20$6.1%20billion%20in%202034

[36] Elizabeth Williams, "Medicaid Coverage of and Spending on GLP-1s," *KFF*, January 16, 2026, https://www.kff.org/medicaid/medicaid-coverage-of-and-spending-on-glp-1s/

[37] "Costly GLP-1 Drugs are Rarely Covered for Weight Loss by Marketplace Plans," *KFF*, June 12, 2024, https://www.kff.org/affordable-care-act/costly-glp-1-drugs-are-rarely-covered-for-weight-loss-by-marketplace-plans/

[38] Gary Claxton et al., "Health Benefits In 2025: Family Premiums Rise 6 Percent, Large Employers Increase Coverage Of GLP-1s For Weight Loss," *Health Affairs,* October 22, 2025, https://www.healthaffairs.org/doi/10.1377/hlthaff.2025.01106

[39] Daniel Gilbert, "Patients navigate an 'absolutely insane' maze to afford weight-loss drugs," *The Washington Post*, May 25, 2025, https://www.washingtonpost.com/business/2025/05/24/weight-loss-drugs-insurance-coverage/

In recent years, policymakers have been trying to figure out how to facilitate broader patient access to GLP-1s to treat obesity. In November 2024, the Biden Administration issued a proposed rule that also would have facilitated broad coverage of anti-obesity medications in both Medicare Part D and Medicaid. The Trump Administration, however, refused to finalize this rule, suggesting it was too expensive.[40] Instead, the Administration opted to pursue a demonstration program through the Center for Medicare and Medicaid Innovation called the Better Approaches to Lifestyle and Nutrition for Comprehensive Health (BALANCE) model. Under the BALANCE model, CMS will negotiate pricing and coverage terms for GLP-1s with manufacturers. Then Medicare Part D plans and state Medicaid programs could choose whether to participate and cover the drugs. In April 2026, however, the BALANCE demonstration fell apart because plans opted not to participate in the model.

When the BALANCE model collapsed, the Trump Administration extended its short-term model, known as the Medicare GLP-1 Bridge, through December 2027. Under this model, taxpayers exclusively foot the bill to provide access to these weight-loss drugs with fixed cost-sharing for people with Medicare. This politically-motivated, short-term fix is fraught with challenges. The Trump Administration approach offers no consistent coverage for a medication that many patients need to take for life, and it lets stakeholders side-step their responsibility to cover the cost of sustained access to these life-changing medications. In light of the Trump Administration's failure to pursue lasting and available administrative avenues, like the Biden Administration's proposed rule, more must be done to ensure access to GLP-1s for the United States population at a sustainable cost. Senate Democrats seek viable solutions to ensure consistent, affordable access to GLP-1s across insurance markets.

Using a "subscription model" to pay for GLP-1s may be a more effective approach to addressing access and affordability challenges. Under a subscription model, a payer pays a manufacturer a set fee for unlimited usage of a drug over a period of time, rather than paying for drugs on a per-unit basis. Subscription models could be effectuated by providing direct lump sum payments to manufacturers or by maintaining current payment approaches in different markets and requiring manufacturers to pay rebates that would equalize final net prices to the agreed upon price under the model.

Subscription models have successfully lowered costs and expanded patient access to population health drugs in the past, such as medications to treat Hepatitis C.

- In 2016, Australia implemented the first major subscription model, paying four drugmakers $766 million for an unlimited five-year supply for Hepatitis C medications. Before the program, only 10,180 Australian patients had received Hepatitis C treatment. By the end of 2021, the number skyrocketed to 95,395 patients—over half of Australia's

[40] "Fact Sheet: President Donald J. Trump Announces Major Developments in Bringing Most-Favored-Nation Pricing to American Patients," The White House, November 6, 2025, https://www.whitehouse.gov/fact-sheets/2025/11/fact-sheet-president-donald-j-trump-announces-major-developments-in-bringing-most-favored-nation-pricing-to-american-patients/; "President Trump on Lowering Price of Weight Loss Drugs," *C-SPAN*, November 6, 2025, https://www.c-span.org/program/white-house-event/president-trump-on-lowering-price-of-weight-loss-drugs/668619

2015 Hepatitis C population.[41] Based on its first two years of data, the program was projected to save Australia $4.9 billion compared to traditional pricing.[42]

- Louisiana's Medicaid program implemented a subscription model in 2019. In exchange for per-unit payments capped at $35 million per year, Gilead agreed to supply the Louisiana Medicaid program with an unlimited five-year supply of Hepatitis C medication.[43] By the end of the program's fourth year, it had treated 30,259 patients—67.4 percent of the state's Hepatitis C-positive population.[44] The Louisiana Department of Health estimated that the model saved over $143 million in 2023 alone.[45]
- In 2022, the U.K. launched a pilot of a subscription model for antibiotics intended to help give manufacturers market predictability and stimulate investment in drugs that treat deadly superbugs.[46] The U.K. is now expanding the model to antimicrobials.

Subscription models may be most effective when the covered therapy would cause a significant spending increase under traditional payment models and where there are multiple manufacturers with competing drugs. Drugs may also need to be easy to manufacture at scale, given that a subscription model would likely provoke a significant increase in utilization. GLP-1s arguably meet these criteria.

Senate Democrats are interested in exploring whether subscription models could be used to lower costs and expand access to population health drugs, such as GLP-1s. We are interested in using subscription models to expand access to GLP-1s for treatment of obesity in the Medicare, Medicaid, commercial, and employer markets. We are seeking feedback on how to design such models and the following specific topics:

- Should there be separate subscription models for government health programs (e.g., Medicare, Medicaid) and private markets (e.g., commercial, employer)?
- Should participation in such models be mandatory for plans? Why or why not?
- How should these models be funded? If Senate Democrats were to consider member-weighted assessments on plans as a funding mechanism, what would the financial impact be on health plans?
- What GLP-1 indications should be covered under such models?

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[41] Phyo Aung et al., "Time-to-hepatitis C treatment initiation among people who inject drugs in Melbourne, Australia," *Epidemiology and Infection* 151 e84 (2023): 1-9, https://www.cambridge.org/core/services/aop-cambridge-core/content/view/0E1B74336E9CA0F958C8522F74875DA7/S0950268823000675a.pdf/timetohepatitis_c_treatment_initiation_among_people_who_inject_drugs_in_melbourne_australia.pdf

[42] Suerie Moon and Elise Erickson, "Universal Medicine Access through Lump-Sum Remuneration — Australia's Approach to Hepatitis C," *The New England Journal of Medicine* 380, no. 7 (2019): 607-610, https://www.kslegislature.gov/li_2020/b2019_20/committees/ctte_spc_2019_financial_institutions_insurance_1/documents/testimony/20191003_58.pdf

[43] Harry H. Liu et al., "Subscription Models for Prescription Drugs," *RAND*, May 21, 2020, https://www.rand.org/content/dam/rand/pubs/perspectives/PEA200/PEA289-1/RAND_PEA289-1.pdf

[44] James M. Flynn et al., "Subscriptions to Prescriptions: Lessons from Louisiana's effort to eliminate Hepatitis C," *National Bureau of Economic Research*, no. 33617, March 2025, https://www.nber.org/system/files/working_papers/w33617/w33617.pdf

[45] "Louisiana Medicaid Preferred Drug List: Program Overview and Results," *MagellanRx*, December 15, 2023, https://www.ldh.la.gov/assets/docs/LegisReports/PreferredDrugList/LAMAnnualPDLReport2023.pdf

[46] Sophie Willis, "Everything you need to know about the NHS antibiotic subscription model," *The Pharmaceutical Journal*, September 26, 2024, https://pharmaceutical-journal.com/article/feature/everything-you-need-to-know-about-the-nhs-antimicrobial-resistance-subscription-model

- On what cycle and under what circumstances should model agreements with manufacturers be renegotiated (e.g., new market entrants/technologies, new indications, new clinical and safety data)?
- What other types of drugs beyond GLP-1s could be good candidates for subscription models and why?
- With respect to Medicare, how should any new subscription model interact with the Medicare drug price negotiation program?

Addressing Launch Prices

Launch prices for new drugs are also increasing and putting financial strain on patients and taxpayers in the United States. Prices for new drugs in the United States have doubled in recent years, with the median annual list price for new drugs over $370,000 in 2024.[47] The United States could save over $1 billion annually if launch prices were aligned to cost-effective pricing.[48] **Senate Democrats request feedback on how and whether Congress could hold pharmaceutical manufacturers more accountable for excessively high launch prices and bring more transparency to manufacturer launch price decisions.**

[47] 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/

[48] Foluso Agboola et al., "Launch Price and Access Report," Institute for Clinical and Economic Review, October 23, 2025, https://icer.org/wp-content/uploads/2025/10/ICER_2025_Launch-Price-and-Access-Final-Report_For-Publication.pdf

Section II: Enhancing Prescription Drug Affordability

The prices manufacturers charge for prescription drugs are not the only reason patients in the United States are burdened by high drug prices. Virtually every stakeholder in the prescription drug supply chain makes more money when prices are high. For example, some supply chain stakeholders are paid based on fees that are linked to a drug's list price—which often means that, the higher the list price is, the higher the fee that stakeholder obtains. Other stakeholders make money based on drug margin or spread, selling drugs for substantially higher prices than the cost of the drug to the stakeholder. These supply chain dynamics can create perverse incentives to keep drug list prices high. By the time the drug reaches a patient, every stakeholder has attempted to arbitrage as much value as possible off that drug, which often inflates prices and leaves patients and taxpayers holding the bag.

Senate Democrats request feedback on policy options that would: (1) enhance patient affordability in Medicare by directly lowering out-of-pocket costs; and (2) build on Congress's work to address perverse incentives in the prescription drug supply chain that keep drug prices high.

I. Lowering Patient Out-of-Pocket Costs

Democrats–without a single Republican vote–passed landmark legislation in 2022 to reduce out-of-pocket costs for seniors and people with disabilities on Medicare. Among other things, these policies capped annual patient out-of-pocket costs in Part D at $2,000 starting in 2026, capped monthly insulin cost-sharing at $35, and made recommended vaccines free. In the first half of 2024 alone (before the out-of-pocket cap fully went into effect), these provisions saved patients in Medicare an estimated $1 billion in out-of-pocket costs.[49] The $2,000 Part D cap was projected to save approximately 11 million Medicare beneficiaries an average of $600 each in out-of-pocket drug costs by 2025, with enrollees who take high-cost drugs often saving thousands of dollars a year.[50]

Too many seniors, however, still cannot afford needed medications. Senate Democrats request feedback on the following policy options, which would directly lower out-of-pocket costs in Medicare and help make prescription drugs more affordable.

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[49] "Biden-Harris Administration's Inflation Reduction Act Saves Medicare Enrollees Nearly $1 Billion in Just the First Half of 2024," United States Department of Health and Human Services, October 22, 2024, https://us.pagefreezer.com/en-US/wa/browse/0a7f82bb-be6e-448a-ae11-373d22c37842?find-by-timestamp=2025-01-02T05:49:59Z&url=https:%2F%2Fwww.hhs.gov%2Fabout%2Fnews%2F2024%2F10%2F22%2Fbiden-harris-administrations-inflation-reduction-act-saves-medicare-enrollees-nearly-1-billion-just-first-half-2024.html&timestamp=2025-01-02T07:03:02Z

[50] "Inflation Reduction Act Research Series: Projecting the Impact of the $2,000 Part D Out-Of-Pocket Cap for Medicare Part D Enrollees with High Prescription Drug Spending," Assistant Secretary for Planning and Evaluation, Office of Health Policy, January 13, 2025, https://aspe.hhs.gov/sites/default/files/documents/ee9b0f2bf15e69d7e3c7ca7618eaa2af/projecting-impact-part-d.pdf

Out-of-Pocket Caps

Research consistently shows that increases in out-of-pocket drug costs can cause patients to skip medication doses, delay refills, or cut pills in half.[51] Capping cost-sharing reduces costs for patients and can lead to better medication adherence and health outcomes, especially for Medicare beneficiaries, who are more likely than the general population to have multiple chronic conditions, recurring prescription needs, and live on fixed incomes. Democrats passed a law in 2022 capping Medicare beneficiaries' insulin costs at $35 per month. Had this policy been in effect in 2020, an estimated 1.5 million Medicare beneficiaries would have saved over $750 million in out-of-pocket costs.[52] A 2026 study in *JAMA* found that the Medicare insulin cap led to substantial reductions in insulin cost-sharing, increased access to insulin, increased adherence to insulin regimens, and better health outcomes for seniors.[53]

Senate Democrats request feedback on whether Congress should cap cost-sharing for additional types of drugs in Medicare to help improve access to medicine and health outcomes for other chronic diseases and conditions. We request expert and stakeholder assistance in identifying categories of drugs that are: (1) highly-rebated; and (2) should be considered "chronic care" medications where such cost-sharing caps might have the greatest impact in terms of access, affordability, and health outcomes. Senate Democrats also request feedback on whether cost-sharing caps for chronic care medicines should be structured as individual caps by drug type (e.g., a $35 cap on each 30-day supply for asthma inhalers) versus an overall monthly cap for all medicines that qualify as chronic care drugs (e.g., a higher monthly cap on total chronic care drug costs per beneficiary).

Senate Democrats are also entertaining proposals to put an out-of-pocket cap in Traditional Medicare (Parts A and B) and request feedback on this proposal among others to make Part B drugs more affordable to beneficiaries.

Improvements to Medicare Low-Income Assistance Programs

Through the IRA, Democrats took steps to improve the low-income subsidy (LIS), or "Extra Help" program that helps low-income seniors afford their prescription drugs. These policies eliminated partial benefits that offered limited cost-sharing support to select enrollees, ensuring all enrolled seniors and people with disabilities receive full benefits.

Today, the LIS program is available to people with incomes below 150 percent of the Federal Poverty Line (FPL) and assets below roughly $17,000 to $18,000 for an individual. With LIS, cost-sharing for brand name drugs is never more than $12.65 and $5.10 for generics.[54] For the

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[51] Farrah Nekui et al., "Cost-related medication nonadherence and its risk factors among Medicare beneficiaries," *Medical Care* 59, no. 1 (2021): 13–21, https://pubmed.ncbi.nlm.nih.gov/33298705/; Jorge L. De Avila et al., "Prevalence and persistence of cost-related medication nonadherence among Medicare beneficiaries at high risk of hospitalization," *JAMA Network Open* 4, no. 3 (2021): e210498, https://pubmed.ncbi.nlm.nih.gov/33656528/

[52] Bisma A. Sayed et al., "Insulin Affordability and the Inflation Reduction Act: Medicare Beneficiary Savings by State and Demographics," Office of the Assistant Secretary for Planning and Evaluation, October 2, 2023, https://www.ncbi.nlm.nih.gov/books/NBK616488/

[53] Dongzhe Hong, et al., "Out-of-Pocket Spending for Insulin by Medicare Beneficiaries After Monthly Caps," *JAMA Internal Medicine* 186, no. 6 (2026): 723-731, https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2847533

[54] "Help with drug costs," Medicare, accessed June 5, 2026, https://www.medicare.gov/basics/costs/help/drug-costs

over 13 million Medicare beneficiaries enrolled in LIS, the program saves each person $5,700 on average annually.[55] However, the asset test creates an administrative burden that prevents financially vulnerable beneficiaries from accessing essential health care and prescription drugs. Low-income seniors and people with disabilities are disincentivized from saving modest amounts for emergencies or retirement to remain eligible for LIS.

Senate Democrats request feedback on whether we should raise the LIS income eligibility threshold to 200 percent FPL (an annual income of $31,000 for an individual in 2026) and eliminate the asset limit. Expanding eligibility and eliminating the asset test would help more Medicare beneficiaries afford needed prescriptions, improve medication adherence and health outcomes, and reduce financial hardship. Additionally, Senate Democrats request feedback on whether we should increase the eligibility threshold for Medicare Savings Programs that assist beneficiaries in paying for their Medicare cost-sharing to 200 percent as well. Aligning the eligibility between the programs offering financial assistance will simplify the experience of low-income seniors during enrollment. Senate Democrats welcome additional input on how to improve enrollment, uptake, and administration of LIS benefits.

Distortions in Coinsurance & Deductibles

Discounts and rebates manufacturers pay to PBMs and health plans after a drug is dispensed are not typically taken into account when plans calculate patient cost-sharing amounts in the deductible phase or when coinsurance applies. Instead, cost-sharing in those contexts is typically based on amounts that more closely approximate higher drug list prices.

Rebates continue to grow as a percentage of overall drug spending in Medicare Part D, which may be contributing to higher cost-sharing for patients. An analysis in *JAMA* found that rebate growth was associated with a $13 average increase in Medicare beneficiary cost-sharing per prescription between 2014 and 2018.[56] During that period, rebates in Part D grew 162 percent, climbing from $16.8 billion in spending in 2014 to $42.5 billion by 2018.[57] A MedPAC analysis of 2020 data suggests manufacturers rebate approximately 22 percent of Part D spending back to plan sponsors and PBMs.[58] In 2021, manufacturers paid approximately $48.6 billion in Part D rebates.[59] For 2024, MedPAC estimates manufacturers paid $77 billion in Part D rebates.[60]

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[55] "Understanding the Extra Help with Your Medicare Prescription Drug Plan," Social Security Administration, January 2026, https://www.ssa.gov/pubs/EN-05-10508.pdf; Juliette Cubanski and Anthony Damico, "Key Facts About Medicare Part D Enrollment, Premiums, and Cost Sharing in 2025," *KFF*, July 16, 2025, https://www.kff.org/medicare/key-facts-about-medicare-part-d-enrollment-premiums-and-cost-sharing-in-2025/

[56] Kai Yeung et al., "Association of Branded Prescription Drug Rebate Size and Patient Out-of-Pocket Costs in a Nationally Representative Sample, 2007-2018," *JAMA Network Open* 4, no.6 (2021): e2113393, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780950

[57] "Drug pricing's $268 billion non-event," 46brooklyn, January 21, 2020, https://www.46brooklyn.com/research/2020/1/21/2018-medicare-part-d-data-review-sxfn7

[58] Tara Hayes et al., "Analysis of Part D data on drug rebates and discounts," MedPAC, September 30, 2022, https://www.medpac.gov/wp-content/uploads/2021/10/DIR-Slides-MedPAC-29-Sept-2022.pdf.

[59] John E. Dicken, "CMS Should Monitor Effects of Rebates on Drug Coverage and Spending," Government Accountability Office, September 19, 2023, https://www.gao.gov/assets/gao-23-107056.pdf

[60] Tara Hayes et al., "The Medicare prescription drug program (Part D): Status report," MedPAC, January 15, 2026, https://www.medpac.gov/wp-content/uploads/2025/08/Tab-L-Part-D-status-report-Jan-2026.pdf

Cost-sharing in the Medicare Part D program also appears to be shifting away from copayments and toward coinsurance, where beneficiaries are more exposed to cost-sharing based on higher list prices. For example, one analysis found that, in 2025, 83 percent of standalone Prescription Drug Plans (PDPs) have three coinsurance tiers, which is a 57 percent increase compared to 2024.[61] Another analysis found that standalone PDP use of coinsurance for preferred brand drugs increased from 9.9 percent in 2020 to 71.9 percent in 2024.[62] Use of coinsurance has grown in the MA market as well, with 63 percent of plans having two or more coinsurance tiers in 2025 relative to 18 percent in 2024.[63]

Basing cost-sharing in the deductible phase and when coinsurance applies on net drug prices could result in substantial savings on out-of-pocket drug costs for patients and would more accurately reflect the ultimate prices plans pay for prescription drugs. **Senate Democrats request feedback on approaches to basing coinsurance and cost-sharing in the deductible phase on net price**. One such proposal is the bipartisan policy the Finance Committee passed on a unanimous basis in 2023 as part of our PBM reform package. That proposal would have based coinsurance on net price for a subset of highly-rebated drugs that treat chronic conditions in Medicare Part D. Ideally, however, any policy requiring cost-sharing to be based on net prices would apply to a broader array of drugs so more patients can benefit from lower cost-sharing.

Congress could also consider new oversight and program integrity policies that address situations when PBMs penalize manufacturers for list price reductions or provide more favorable formulary coverage to higher list price products over lower list price alternatives. PBMs and the vertically integrated insurers they are often affiliated with may have multiple financial incentives to prefer higher-priced drugs over lower-cost alternatives (e.g., price-linked fees, rebate guarantee dynamics, incentives created by the Medical Loss Ratio, incentives created by Part D's benefit design and the way the program is subsidized). For example, more expensive brand drugs often have more favorable formulary placement than lower-cost generics in Medicare Part D.[64] The Federal Trade Commission (FTC) has alleged that PBMs put upward pressure on insulin prices to extract more rebates and fees from manufacturers, which is consistent with findings from a bipartisan Senate Finance Committee investigation into insulin manufacturer contracts with PBMs.[65] In cases where manufacturers have launched both high list price-high rebate versions of their products and low list price versions that factored discounts in upfront, PBMs often

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[61] "Medicare Prescription Payment Plan May Help Enrollees Facing More Coinsurance in 2025," *Avalere Health*, January 7, 2025, https://advisory.avalerehealth.com/insights/medicare-prescription-payment-plan-may-help-enrollees-facing-more-coinsurance-in-2025

[62] Erin Trish et al., "Cost Sharing for Preferred Branded Drugs in Medicare Part D," *JAMA* 333, no. 13 (2025): 1170-1172, https://jamanetwork.com/journals/jama/fullarticle/2830569?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jama.2024.28092

[63] Avalere Health, "Medicare Prescription Payment Plan."

[64] Erin Trish et al., "U.S. Consumers Overpay for Generic Drugs," *USC Leonard D. Schaeffer Institute for Public Policy & Government Service*, May 31, 2022, https://schaeffer.usc.edu/research/u-s-consumers-overpay-for-generic-drugs/

[65] Lina M. Khan et al., "Administrative Complaint In the Matter of Caremark Rx, LLC; Zinc Health Services, LLC; Express Scripts, Inc.; Evernorth Health, Inc.; Medco Health Services, Inc.; Ascent Health Services LLC; OptumRx, Inc.; OptumRx Holdings, LLC; and Emisar Pharma Services LLC.," Federal Trade Commission, November 26, 2024, https://www.ftc.gov/system/files/ftc_gov/pdf/612314.2024.11.26_part_3_administrative_complaint_-_revised_public_redacted_version.pdf ; "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," United States Senate Finance Committee, 2019, https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf

preferred the high list price-high rebate versions.[66] Because patient cost-sharing is typically based on pricing benchmarks that more closely approximate list prices, these dynamics can increase costs for patients. **Senate Democrats also request feedback on how best to address this issue in the absence of a net price policy.**

Generic Drug Price Markups

In 1984, Congress passed landmark legislation, the *Drug Price Competition and Patent Term Restoration Act* (the "Hatch-Waxman Act"), which established a framework for generic drug approvals. Thanks to Hatch-Waxman, generic medicines now account for approximately 90 percent of prescriptions filled in the U.S.[67] The "grand compromise" under Hatch-Waxman was designed to reward innovation by allowing brand medicines to remain on the market without competition for a period of time to recoup their investments before allowing lower-cost generics to enter. Because generic medicines typically behave like commodities, when generics enter the market, drug prices tend to drop precipitously. Prices often fall by as much as 70 to 90 percent once robust generic competition develops.[68]

Supply chain stakeholders (e.g., PBMs, pharmacies, wholesalers), however, can mark up generic pricing after drugs leave the hands of the manufacturer. Unfortunately, generic drug prices are often egregiously inflated in Medicare Part D, which threatens to undermine Hatch-Waxman's grand compromise and leaves patients and taxpayers bearing unnecessarily high costs. Based on 2021 data, Part D plans reimbursed generic drugs at a mean of 5.4 times their acquisition costs, with some generic drug price markups as high as 7,000 percent.[69] Another analysis found that Medicare paid $2.86 billion more on 184 common generic drugs than cash pay prices available at Costco.[70] Many companies that offer generic medicines at cash pay or cost-plus pricing charge significantly less for generic medicines than reimbursements from Medicare Part D plans, despite PBMs and wholesalers having substantially more leverage than these smaller companies to negotiate lower price points. One analysis suggested Medicare could save $3 billion if generic pricing in Part D reflected cost-plus pricing offered in the cash pay market.[71] The *Wall Street Journal* also found that Medicare pays as much as 100 times more for certain specialty generic drugs, such as cancer medication imatinib, relative to cash pay prices.[72]

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[66] Adam Fein, "The Warped Incentives Behind Amgen's Humira Biosimilar Pricing–And What We Can Learn from Semglee and Repatha," *Drug Channels*, February 7, 2023, https://www.drugchannels.net/2023/02/the-warped-incentives-behind-amgens.html

[67] "2025 U.S. Generic & Biosimilar Medicines Savings Report," *Association for Accessible Medicines*, 2025, https://accessiblemeds.org/resources/reports/2025-savings-report/

[68] "How Generic Competition Advances Public Health by Improving Access to Affordable Medication," Food and Drug Administration, November 17, 2025, https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices

[69] Inmaculada Hernandez et al., "Reimbursement to Pharmacies for Generic Drugs by Medicare Part D Sponsors," *JAMA* 330, no. 24 (2023): 2390-2392, https://jamanetwork.com/journals/jama/fullarticle/2812780

[70] Erin Trish et al., "Comparison of Spending on Common Generic Drugs by Medicare vs Costco Members," *JAMA Internal Medicine* 181, no. 10 (2021): 1414-1416, https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2781810

[71] Hussain S. Lalani et al., "Potential Medicare Part D Savings on Generic Drugs From the Mark Cuban Cost Plus Drug Company," *Annals of Internal Medicine* 175, no. 7 (2022): 1053-1055, https://doi.org/10.7326/M22-0756

[72] Joseph Walker, "Generic Drugs Should Be Cheap, but Insurers Are Charging Thousands of Dollars for Them," *The Wall Street Journal*, September 11, 2023, https://www.wsj.com/health/healthcare/generic-drugs-should-be-cheap-but-insurers-are-charging-thousands-of-dollars-for-them-ef13d055?gaa_at=eafs&gaa_n=AWEtsqfNbFSdxBAbNLDuXxYi8bdUwxQVjNfoCn7toHVS4ixdDmLKTeGKdnrVc8FSGOo%3D&gaa_ts=691f5075&gaa_sig=jACsWmJRi6qohl9WuzM3Oo-xVPYBsCu0P8udYeU3N7LKalCHuchyLQMpazcrRaAKTnD2-kndhR1Fre1wbrEbXA%3D%3D

The exact cause of generic drug price distortions is difficult to pinpoint due to the opacity of the prescription drug supply chain. Excessively high generic prices, however, generally do not appear to be a result of manufacturer price gouging. Most generic drugs are commodities, which can cause race-to-the-bottom pricing dynamics between competing manufacturers in the generic market. Benchmark prices generated by the National Average Drug Acquisition Cost (NADAC) survey—which estimates pharmacy drug acquisition costs—also tend to be much lower than the prices Medicare Part D pays for generic medicines.[73] Thus, the margin between drug acquisition cost and the ultimate prices charged for generic medicines is likely being captured by other stakeholders across the prescription drug supply chain, such as wholesalers, PBMs, and pharmacies.

It is a profound market failure that health insurers are not providing affordable access to lower-cost, commoditized generics. Due to grossly inflated generic prices, many Medicare beneficiaries and patients with other forms of coverage are not even using the insurance they pay a monthly premium for to purchase generic medicines and are instead turning to the cash pay market. Overall, cash pay accounts for approximately 10 percent of all generic prescriptions in the United States.[74] Even where patients use their insurance and are insulated from inflated generic drug costs in terms of their out-of-pocket costs, beneficiaries bear the cost through higher Medicare Part D premiums and taxpayers unfairly bear the burden of inflated generic drug pricing in the form of higher Medicare program costs.

Senate Democrats are interested in policy ideas that would bring "cost-plus" style pricing into Medicare Part D for generic medicines. NADAC survey data could be used in a variety of ways to help facilitate cost-based pricing for drug ingredient costs and ensure generic pricing in Part D is not predatorily inflated.[75] For example, a NADAC-based benchmark (plus a dispensing fee) could be used as a ceiling on Part D negotiated prices for generic drugs. Alternatively, Congress could also adjust Part D subsidies when plans inflate generic drug prices, pursue program integrity approaches to penalize this behavior, or require plans to reimburse patients for cash pay generic drug purchases.

Part D Market Impact

Policies that reduce patient out-of-pocket costs on drugs are likely to increase Part D premiums. The drug price reduction policies outlined in the previous section are likely to offset some of these effects, but it is possible that Congress will have to take additional steps to contain premiums in the Part D market. This is especially true of the standalone PDP market, since standalone PDPs do not have access to rebates provided to MA plans. In 2025, MedPAC estimates MA plans received $86 billion total in rebates, with approximately $15 billion of that

[73] Hernandez et al., "Reimbursement to Pharmacies."
[74] Lu Chen, Brian Bush, Gian King et al., "The Cash Generics Opportunity in Health Care," BCG, May 22, 2024, https://www.bcg.com/publications/2024/cash-generics-opportunity-in-health-care
[75] Congress should also enact policies originally considered as part of the Finance Committee's bipartisan PBM reform package that would make NADAC reporting mandatory for pharmacies and include more pharmacy types (e.g., mail order and specialty pharmacies) in the survey. This policy change would ensure NADAC data more accurately reflects acquisition costs and includes specialty medicines.

amount going toward Part D premium reductions and benefit enhancements.[76] MA-PDs use as much as 15 to 20 percent of MA rebates to buy down Part D premiums or enhance Part D benefits.[77] Standalone PDPs are not able to subsidize Part D premiums and benefits in the same manner, which creates an unlevel playing field in the broader Part D market.

Ensuring robust competition and plan options in the standalone PDP market is important to preserving Traditional Medicare as a viable coverage option for seniors and people with disabilities. **Senate Democrats therefore request feedback on how best to stabilize Part D market premiums, particularly in the standalone PDP market.** We specifically request feedback on the following policy options:

- Changing the National Average Monthly Bid Amount (NAMBA) calculation (e.g., calculating separate NAMBAs for MA-PDs and PDPs, calculating regional NAMBAs);
- Amending or calculating separate risk adjustment between MA-PDs and PDPs;
- Increasing manufacturer liability in the catastrophic phase of Part D;
- Require MA-PDs to submit combined bids for their MA-PD and PDP populations;
- Enhancing CMS authority to reject Part D bids; and
- Extending a version of the IRA's Part D premium stabilization policy, which currently expires at the end of 2029.

II. Addressing Perverse Dynamics in the Supply Chain

Addressing perverse incentives in the prescription drug supply chain has long been an area of interest for the Finance Committee. In 2018, the Committee minority staff released a report entitled *A Tangled Web: An Examination of the Drug Supply and Payment Chains*, which explored business and financial relationships between manufacturers, wholesalers, PBMs, health plans, and pharmacies.[78] During the 118th Congress, the Finance Committee worked on a bipartisan basis to begin to address perverse incentives with respect to PBMs. In January 2026, provisions that prohibit PBMs from being compensated based on the price of a drug in Medicare Part D and sweeping new transparency requirements passed into law as part of the *Consolidated Appropriations Act of 2026*.

Congress should build on the progress made under the bipartisan PBM reforms by eliminating more distortions in the prescription drug supply chain. Senate Democrats request feedback on the following issues and proposals.

Games & Abuses Due To Vertical Integration

The prescription drug supply chain in the United States is becoming more vertically integrated. The three largest PBMs–CVS Caremark, Express Scripts, and OptumRx–are vertically integrated with other components of the supply chain, including health plans, pharmacies (retail, specialty

[76] "Medicare and the Health Care Delivery System," MedPAC, June 12, 2025, https://www.medpac.gov/wp-content/uploads/2025/06/Jun25_MedPAC_Report_To_Congress_SEC.pdf
[77] "The Medicare Advantage program: Status report," in *Report to the Congress: Medicare Payment Policy*, MedPAC, March 13, 2025, https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch11_MedPAC_Report_To_Congress_SEC.pdf
[78] "A Tangled Web: An examination of the drug supply and payment chains," United States Senate Finance Committee, June 2018, https://www.finance.senate.gov/imo/media/doc/A%20Tangled%20Web.pdf

and mail order), wholesalers, and private labelers.[79] While the extent and types of mergers vary, each of the three largest PBMs is integrated with a health plan and at least one pharmacy channel. The Medicare Part D market in particular is heavily vertically integrated. As of 2021, the five largest Part D sponsors–all of which are vertically integrated with other parts of the supply chain–accounted for more than 90 percent of Part D enrollees.[80]

Because Medicare Part D regulates prescription drug plans–and generally does not regulate or have clear line of sight into other entities that may be affiliated with such plans–plan sponsors and their parent companies can potentially game the Part D program through vertical integration. For example, vertically integrated entities may have incentives to charge plans inflated drug costs through their affiliated pharmacy channels so the vertically integrated entity can simultaneously capture drug margin through its pharmacies and draw down higher Part D subsidies from Medicare at the plan level. In other words, Medicare may be subsidizing supply chain stakeholder drug price markups. There is some evidence that vertically integrated PBMs pay their affiliate pharmacies more than non-affiliated pharmacies, including in the Part D program, and apply egregious price markups on drugs dispensed primarily through their affiliated specialty pharmacy channels.[81] Specialty pharmacy appears to be a particularly important earnings driver for vertically integrated health care companies. In 2025, the big three PBMs' specialty pharmacies generated a combined $198.5 billion in revenue and "specialty dispensing accounted for more than one-third of PBMs' total gross profits."[82] The FTC also estimated that between 2017 and 2022, the three largest PBMs generated $7.3 billion in revenue over drug acquisition costs for specialty generics alone, $1.4 billion of which came from Part D.[83]

Medicare Part D's bidding process, which helps determine plan subsidy amounts from the Part D program, currently accounts for sponsor (i.e., plan) margin and requires such margin to relate to benefit value and premiums.[84] The Part D bidding process, however, does not consider overall margin accruing to a vertically integrated entity–even though Part D could be subsidizing that margin in the form of higher drug costs. **Senate Democrats request feedback on whether Congress should require CMS to develop a new standard for how margin is considered for vertically integrated sponsors in the Part D bidding process in order to prevent program abuses and put downward pressure on drug costs.**

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[79] Adam Fein, "Mapping the Vertical Integration of Insurers, PBMs, GPOs, Specialty Pharmacies, and Healthcare Services: DCI's 2026 Update," *Drug Channels*, April 14, 2026, https://www.drugchannels.net/2026/04/mapping-vertical-integration-of.html

[80] Tara Hayes et al., "The Medicare prescription drug program (Part D): Status report," MedPAC, January 13, 2023, https://www.medpac.gov/wp-content/uploads/2023/01/MedPAC-Part-D-status-report-Jan-2023.pdf

[81] "Assessing postsale rebates for prescription drugs in Medicare Part D" in *Report to the Congress: Medicare and the Health Care Delivery System*, MedPAC, June 15 2023, https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch2_MedPAC_Report_To_Congress_SEC.pdf; "Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers," Federal Trade Commission, January 2025, https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf

[82] Adam Fein, "The Top 15 Specialty Pharmacies of 2025: PBM-Affiliated Pharmacies Dominate While Health Systems and Independents Gain Ground," *Drug Channels*, April 21, 2026, https://www.drugchannels.net/2026/04/the-top-15-specialty-pharmacies-of-2025.html

[83] Federal Trade Commission, "Specialty Generic Drugs."

[84] "Instructions for completing the Prescription Drug Plan Bid Pricing Tool for contract year 2025," Centers for Medicare & Medicaid Services, April 5, 2024, https://www.cms.gov/files/document/cy2025-part-d-bpt-instructions20240405.pdf; Christi A. Grimm, "CMS should strengthen its prescription drug event guidance to clarify reporting of sponsor margin for Medicare Part D bids," Department of Health and Human Services, November 22, 2021, https://oig.hhs.gov/documents/audit/6800/A-03-17-00001-Complete%20Report.pdf

PBM Private Label Drugs

As policymakers at the federal and state level continue to clamp down on PBM practices related to rebates and fees, PBMs are likely to turn to other strategies to try to make up lost revenue. One such strategy is marketing PBM-owned private label drugs with inflated prices. A private label drug is a medicine manufactured by one company but sold under another company's name or label. In other words, PBMs are buying generic and biosimilar medicines from manufacturers and selling them under a label the PBM owns. The company that labels the drug typically sets the drug's price. All three of the largest PBMs are now affiliated with private labelers: Express Scripts with Quallent, Caremark with Cordavis, and OptumRx with Nuvaila. Experts have warned that vertical integration between PBMs and private labelers threatens to forestall price reductions and harm long-term biosimilar competition.[85]

PBM private labelers also inflate the prices of generics and biosimilars, which allows the margin between the lower price the private labeler acquires the drug for and the higher amount it charges for the product to fall to the insurance conglomerate's bottom line. For example, Fresenius Kabi sells its biosimilar version of Humira (Idacio) to Blue Shield of California for $525.[86] PBM private labelers, however, are charging around $1,300 for their biosimilar versions of Humira. These companies have significantly more covered lives and leverage than Blue Shield of California, which should enable them to purchase at a lower price.[87] It is extremely likely, therefore, that the PBM private labelers are acquiring biosimilar versions of Humira at a lower price than $525, despite the high prices they charge for these products.

Private labelers' markups extend beyond the biosimilar market. Quallent also sells small molecule generics. One investigation found that, if Medicare had bought all of the units of the products that Quallent sold to it in 2023 from Quallent—as opposed to some from Quallent and some from other companies, as actually occurred—Medicare's gross drug expenditures would have risen by $1.2 billion.[88] On blockbuster anti-cancer drug imatinib, Cost Plus Drugs sold a 400mg pill to consumers for roughly $1.55 in 2023.[89] That same year, Quallent charged Medicare $103 per pill for the drug.[90]

Given how much money big insurance companies and their PBM affiliates can make off private-label drugs, it is no surprise that PBM formularies often shift dramatically in favor of drugs marketed under an affiliate private label when such products become available. For

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[85] Michael A. Carrier and Rachel Sachs, "Competitive Concerns from Pharmacy Benefit Managers Selling Their Own Drugs," *Rutgers Law School*, July 31, 2025, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5372944

[86] "Blue Shield of California Slashes Cost of World's Best-Selling Drug," Blue Shield of California, October 1, 2024, https://news.blueshieldca.com/2024/10/01/blue-shield-of-california-slashes-cost-of-worlds-best-selling-drug

[87] Adam Fein, "The Big Three PBMs' 2025 Formulary Exclusions: Humira, Stelara, Private Labels, and the Shaky Future for Pharmacy Biosimilars," *Drug Channels*, January 22, 2025, https://www.drugchannels.net/2025/01/the-big-three-pbms-2025-formulary.html

[88] "How PBMs can use private-labelled drug products as a great escape from anti-steering policies," 46brooklyn, July 22, 2025, https://www.46brooklyn.com/research/welcome-to-private-label-park-nuf485-8h5kw

[89] Hagop Kantarjian and Mary Alma Welch, "Influence of the 'Mark Cuban Effect' on Cancer Drug Prices in the United States: Focus on CML," *The ASCO Post*, February 10, 2023, https://ascopost.com/issues/february-10-2023/influence-of-the-mark-cuban-effect-on-cancer-drug-prices-in-the-united-states-focus-on-cml/

[90] 46brooklyn, "How PBMs can use private-labelled drug products."

example, in 2025, the three largest PBMs favored their own private-label Humira biosimilars on their formularies and excluded nearly all other Humira biosimilars.[91]

Senate Democrats request feedback on how to address marked-up prices on PBM private-label drugs in Medicare Part D. One approach would be requiring PBMs to disclose the spread between their private labeler's acquisition cost on such drugs and the price PBMs charge their Part D and other clients for the same medicines. This policy would likely empower health plans to negotiate better pricing or give government regulators more information to consider in the Part D bid process. Alternatively, Medicare could ban dispensing PBM-owned private label medicines in Part D unless they satisfy a cost-plus pricing standard. **We seek feedback on these and other approaches to rein in inflated markups on private-label prescription drugs.**

PBM Gag Clauses

The PBM industry is heavily consolidated, with the three largest PBMs controlling around 80 percent of the market.[92] PBMs can leverage this market power through the contracting process with their plan clients and manufacturers in ways that could potentially forestall competition. For example, Finance Committee minority staff is aware of terms in PBM-plan contracts that may prohibit their plan clients from contracting–or even entering into discussions–with manufacturers, at least with respect to pricing. These contract terms may make the PBM the "exclusive negotiator" of drug prices for the plan client. Finance Committee minority staff is also aware of "non-solicitation"-style terms in PBM-manufacturer contracts that prohibit manufacturers from providing discounts directly to health plans.

These types of contract terms may interfere with drug supply chain stakeholder business decisions by gagging stakeholders from communicating with each other and inhibiting potential creative arrangements that may help plans contract for drugs at lower price points than what their PBM offers. PBMs may argue that these contract terms are important to preserving the confidentiality of the PBM's pricing information and leverage in negotiations.

Senate Democrats request feedback on whether these types of "exclusive negotiator" and "non-solicitation" clauses should be regulated or prohibited in Medicare Part D and other markets, with the goal of opening up more drug price competition and opportunities for creative arrangements between stakeholders. This would not be the first time Congress acted to address abusive gag clauses in PBM contracts. In 2018, Congress banned PBM gag clauses prohibiting pharmacists from alerting patients about less expensive ways to access the medicines they need at the pharmacy counter.[93]

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[91] Fein, "The Big Three PBMs' 2025 Formulary Exclusions."; Paige Twenter, "Big 3 PBM formularies favor private-label biosimilars," *Becker's Hospital Review*, January 22, 2025, https://www.beckershospitalreview.com/pharmacy/big-3-pbm-formularies-favor-private-label-biosimilars/

[92] Josh Mader, "Pharmacy Benefit Managers: Market Landscape and Strategic Imperatives," *Health Industries Research,* https://www.hirc.com/PBM-market-landscape-and-imperatives; Denise Myshko and Peter Wehrwein, "Beyond the Big Three PBMs," *Managed Healthcare Executive,* December 19, 2022, https://www.managedhealthcareexecutive.com/view/beyond-the-big-three-pbms

[93] *Patient Right to Know Drug Prices Act*, Public Law 115-263, https://www.congress.gov/bill/115th-congress/senate-bill/2554/text

Increasing PBM Accountability for Rising Drug Costs

Per member per month drug costs in Medicare Part D continue to grow year-over-year. Annual changes in drug costs, known as "pharmacy trend," can be driven by drug prices, changes in drug utilization, new drugs coming to market, changes in beneficiary cost-sharing, and other factors. In recent years, actuarial firms have projected increases in Part D drug costs of around five to ten percent annually. In 2025, pharmacy trend jumped to nearly 20 percent due to increased drug utilization, reductions in beneficiary cost-sharing, increased use of GLP-1s, and other factors.[94]

PBMs do not always face meaningful downside risk in their contracts with health plan clients, which may limit their incentives to control drug costs. Many contracts include rebate guarantees, which require the PBM to make payments to their plan clients when they fail to achieve a specified aggregate level of rebates on drugs. Rebate guarantees, however, are opaque, easily gameable, and do not actually guarantee lower net effective costs for plans.[95] Delivering more rebates to a client does not mean that the PBM's formularies prefer the lowest net cost drug. In fact, rebate guarantees could create incentives for PBMs to prefer brand drugs over generics since generics typically do not offer rebates.[96] PBMs with vertically integrated pharmacies can also make money off drug margin, which is another example of a financial incentive PBMs face to inflate drug prices or prefer higher cost drugs.[97]

Senate Democrats request feedback on how to hold PBMs more accountable for containing pharmacy trend and delivering lower net effective costs on drugs. Some health plans and employers are trying to use more creative contracting strategies that could lead to savings if adapted and applied in the Part D program. For example, the California Public Employee Retirement System's (CalPERS) PBM contract requires its PBM to put a multi-million dollar lump sum at-risk if annual pharmacy trend exceeds 6.5 percent.[98] PBMs could also be required to meet net effective cost[99] guarantees (rather than rebate guarantees) or bid for business in Part D based on net effective cost metrics.

Pharmacy Dispensing Fees in Part D

Under Medicare Part D, pharmacy reimbursement is negotiated between health plans (usually through PBMs) and pharmacies. Pharmacy reimbursement is often extremely complex, but it generally consists of a reimbursement rate for the drug itself ("ingredient cost") and a dispensing

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[94] Madeleine Feller et al., "Milliman MedIntel Part D trend insights," *Milliman*, January 15, 2026, https://www.milliman.com/en/insight/medintel-part-d-trend-insights-q3-2025

[95] Paul Lendner, "When is a Brand a Generic? In a Contract with a PBM," *Managed Care Magazine*, March 3, 2024, https://www.managedcaremag.com/archives/2010/9/when-brand-generic-contract-pbm/; Brian Anderson and Gregory Callahan. "PBM Best Practices Series: Effective Contracting," *Milliman*, February 2020, https://us.milliman.com/-/media/milliman/pdfs/articles/pbm-best-practices-effective-pbm-contracting.ashx

[96] Scott Musial, "PBM rebates explained: A guide to 100% pass-through models," *Rightway Health Care*, March 25, 2026, https://www.rightwayhealthcare.com/blog/pbm-rebates-explained

[97] Federal Trade Commission, "Specialty Generic Drugs."

[98] "CalPERS Announces New Pharmacy Benefits Contract With CVS Caremark to Foster Affordability and Improve Quality," CalPERS, July 15, 2025, https://www.calpers.ca.gov/newsroom/calpers-news/2025/calpers-announces-new-pharmacy-benefits-contract-with-cvs-caremark-to-foster-affordability-and-improve-quality

[99] The "net effective cost" is the true per unit cost of a drug after all discounts, rebates, fees, spread pricing, markups, and other economic components are considered.

fee intended to compensate the pharmacy for its services and overhead. Some analyses suggest that dispensing fees in Part D are extremely low, often less than a dollar.[100] According to survey data from pharmacies, the actual cost of per prescription dispensing ranges from $11 to $13.[101] Due in part to dispensing fee shortfalls, pharmacies are often forced to try to make money off of margin on the drugs themselves, specifically the spread between their drug acquisition costs and the ultimate reimbursement they get on the ingredient cost for the same drug from a PBM. This reliance on margin as a form of compensation can increase drug costs for patients and the health care system.

Policies that lower the costs and prices of drugs can therefore have the unintended effect of reducing pharmacy reimbursement, which may in turn have a negative impact on retail pharmacy access. Retail pharmacy access across the United States has been in decline for years, due in large part to reimbursement pressures from a heavily consolidated PBM market.[102] One study found that one in three retail pharmacies that were open in 2010 had closed by 2021, and that closure risk appeared to be highest among independent pharmacies and pharmacies in Black and Latino communities.[103]

A better approach to pharmacy reimbursement would be to reduce reliance on the margin generated by inflated drug prices (i.e., ingredient costs) and instead ensure that dispensing fees adequately compensate pharmacies for the services they provide. Ensuring dispensing fees accurately reflect pharmacy costs may also help enhance predictability in pharmacy finances and improve pharmacy access. **Senate Democrats therefore request feedback on how best to structure minimum pharmacy dispensing fee requirements in Medicare Part D**. For example, Part D could leverage minimum dispensing fees already established by State Medicaid programs based on cost of dispensing surveys. Alternatively, Part D could develop its own minimum dispensing fees based on new or existing cost of dispensing surveys. **We also request feedback on whether and how best to distinguish between pharmacy types when setting minimum dispensing fees (e.g., retail, essential retail, specialty, mail order, long-term care).**

Addressing Price-Linked Compensation

In January 2026, Congress passed a bipartisan law authored by the Finance Committee that prohibits PBMs from being compensated based on the price of a drug in Medicare Part D (referred to as "delinking"). This legislation was inspired by a Finance Committee investigation into insulin contracts between PBMs and manufacturers, which found evidence that price-linked compensation created business incentives to increase drug prices and for PBMs to prefer higher-priced medicines.[104]

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[100] "Healthcare ideas, unstuck," Milligram Health, accessed June 5, 2026, https://milligram-health.com/
[101] "Cost of Dispensing Study," Abt Associates, January 2020, https://www.nacds.org/pdfs/pharmacy/2020/NACDS-NASP-NCPA-COD-Report-01-31-2020-Final.pdf
[102] "The Medicare prescription drug program: Status report," in *Report to the Congress: Medicare Payment Policy*, MedPAC, March 13, 2025, https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch12_MedPAC_Report_To_Congress_SEC.pdf
[103] Jenny S. Guadamuz et al., "More US Pharmacies Closed Than Opened In 2018–21; Independent Pharmacies, Those In Black, Latinx Communities Most At Risk," *Health Affairs*, December 3, 2025, https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00192
[104] U.S. Senate Finance Committee, "Insulin."

PBMs, however, are not the only stakeholders in the prescription drug supply chain that receive compensation linked to the price of a drug. Numerous stakeholders make money on drug spreads or margin (i.e., pocketing the difference between the stakeholder's acquisition/net cost on the drug and the amount such stakeholder charges for the drug to patients or others in the supply chain). Other stakeholders also receive various forms of fees linked to drug prices. For example, drug wholesalers reportedly make money from price-linked fees from manufacturers and buy-and-sell spreads on drugs.[105] **Senate Democrats request more information about price-linked compensation across the prescription drug supply chain and policy ideas to address potential perverse incentives created by these payments.**

Under the Medicare statute, physicians are also entitled to price-linked compensation in the form of add-on payments under Medicare Part B. Specifically, Medicare Part B reimburses physicians for outpatient drugs based on the Average Sales Price[106] plus an add-on payment equal to six percent of ASP.[107] The six percent add-on payment can be used to cover costs associated with administering Part B drugs, such as handling, inventory management, storage, and overhead. Add-on payments may also help ensure smaller practices that may pay more than the ASP to acquire Part B drugs recoup their acquisition costs.[108] There is not a clear rationale, however, as to why the add-on payment should be linked to the price of the underlying drug.

While many factors contribute to physician prescribing decisions, the linkage between the Part B add-on payment and drug prices may create incentives for physicians to prescribe more expensive medicines in some cases. For example, one study found that beneficiaries in Traditional Medicare (where physicians are reimbursed using the ASP+6% methodology) were more likely to be prescribed higher cost drugs in therapeutic areas where less expensive alternatives were available than beneficiaries enrolled in MA.[109] Several studies have found that the ASP+6% methodology may create incentives for physicians to prescribe more expensive cancer medications under certain circumstances.[110] Another study found that, even in the absence of shortages, physicians were more likely to prescribe more expensive forms of intravenous iron despite the existence of lower cost alternatives.[111]

Over the past decade, many policymakers and experts have proposed changes to the ASP+6% payment methodology to address these perverse incentives. For example:

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[105] Elizabeth Seeley, "The Impact of Pharmaceutical Wholesalers on U.S. Drug Spending," Commonwealth Fund, July 20, 2022, https://www.commonwealthfund.org/publications/issue-briefs/2022/jul/impact-pharmaceutical-wholesalers-drug-spending; Senate Finance Committee, "A Tangled Web."; "An Examination of Pharmaceutical Supply Chain Intermediary Margins in the U.S. Retail Channel," submitted by Eastern Research Group to the Department of Health and Human Services, September 27, 2024, https://www.ncbi.nlm.nih.gov/books/NBK611836/pdf/Bookshelf_NBK611836.pdf

[106] ASP is the volume-weighted average sale price of a drug to all purchasers, net of discounts and rebates. Manufacturers report sales data to CMS to calculate the ASP.

[107] Note that sequestration reduces add-on payment amounts.

[108] "Part B drug payment policy issues" in *Report to the Congress: Medicare and the Health Care Delivery System*, MedPAC, June 15, 2015, https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/chapter-3-part-b-drug-payment-policy-issues-june-2015-report-.pdf

[109] Kelly E. Anderson et al., "Prescribing of low‐versus high‐cost Part B drugs in Medicare Advantage and traditional Medicare," *Health Services Research* 57, no. 3 (2022): 537-547, https://doi.org/10.1111/1475-6773.13912

[110] MedPAC, "Part B."

[111] Bryan C. Hambley et al., "Payment Incentives and the Use of Higher-Cost Drugs: A Retrospective Cohort Analysis of Intravenous Iron in the Medicare Population," *American Journal of Managed Care* 26, no. 12 (2020): 516-522, https://doi.org/10.37765/ajmc.2020.88539

- In 2016, the Obama Administration proposed a Medicare demonstration program to test whether replacing the 6 percent add-on payment with an add-on payment of 2.5 percent plus a $16.80 flat fee would change financial incentives for physicians.[112]
- In 2020, the Trump Administration included in its Medicare Part B Most Favored Nation demonstration model a proposal to replace the 6 percent add-on payment with a flat, standardized payment amount for all model drugs.[113]
- MedPAC has also issued a series of policy proposals on this topic. Most recently, in 2022, MedPAC proposed several options, including: (1) maintaining the ASP+6% methodology but capping add-on payments at $175; (2) reducing the percentage add-on payment overtime and combining it with flat dollar payments (e.g., ASP+3%+$21); or (3) paying the lesser of the previous two options.[114]

Senate Democrats request feedback on these and any other policy options that would "delink" physician compensation from drug prices under Medicare Part B.

Inappropriate Pharmacy Rejections

Part D plans and PBMs may also face perverse incentives to create barriers for patients to accessing medication as a mechanism of controlling costs, even when such medications are clinically appropriate for the patient. For example, the HHS Office of the Inspector General (OIG) found that in 2017, Part D sponsors rejected millions of prescriptions when the patient went to fill their prescription at the pharmacy counter often due to prior authorization rules, formulary exclusions, quantity limits, and other forms of utilization management. When beneficiaries appealed these denials, however, the OIG found that 73 percent of rejections were overturned.[115] A 2025 IQVIA study found that, for Medicare beneficiaries who were initially denied a prescription and ultimately overcame the denial, treatment was delayed by an average of 14 to 24 days. Between 10 to 19 percent of these patients experienced a delay of five weeks or longer.[116]

Inappropriate pharmacy rejections cause delays in treatment, drive patients to pursue more expensive or clinically inferior alternatives, or cause patients to abandon attempts to obtain needed medication altogether. **Senate Democrats therefore request feedback on approaches to holding Part D plan sponsors and PBMs accountable for inappropriate pharmacy**

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[112] "CMS proposes to test new Medicare Part B prescription drug models to improve quality of care and deliver better value for Medicare beneficiaries," Centers for Medicare & Medicaid Services, March 8, 2016, https://www.cms.gov/newsroom/fact-sheets/cms-proposes-test-new-medicare-part-b-prescription-drug-models-improve-quality-care-and-deliver

[113] "Most Favored National (MFN) Model," Centers for Medicare & Medicaid Services, November 18, 2020, https://www.cms.gov/priorities/innovation/media/document/mfn-ifc-rule

[114] "Addressing high prices of drugs covered under Medicare Part B" in *Report to the Congress: Medicare and the Health Care Delivery System*, MedPAC, June 15, 2022, https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_Ch4_MedPAC_Report_to_Congress_v3_SEC.pdf

[115] Suzanne Murrin, "Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs," Office of Inspector General, U.S. Department of Health and Human Services, September 18, 2019, https://oig.hhs.gov/documents/evaluation/3141/OEI-09-16-00411-Complete%20Report.pdf

[116] "The Impact of Formulary Controls on Medicare Patients in Five Chronic Therapeutic Areas," The IQVIA Institute, June 16, 2025, https://www.iqvia.com/locations/united-states/library/white-papers/the-impact-of-formulary-controls-on-medicare-patients-in-five-chronic-therapeutic-areas

rejections.[117] For example, should CMS develop a Medicare Part D Star Rating metric related to inappropriate pharmacy rejections? Should inappropriate pharmacy rejection rates be made more transparent through Plan Finder or other mechanisms? How could Congress make Part D appeals processes more efficient for patients?

[117] Senate Democrats intend to explore similar policy solutions and broader reforms related to prior authorization in the commercial market as part of our initiative to deliver health coverage that works for everyone.

Section III: Bolstering Biopharmaceutical Innovation in the United States

In addition to lowering drug prices and out-of-pocket costs for patients, policymakers also must ensure a robust pipeline for biomedical innovation in the United States that will deliver the treatments and cures of tomorrow. Historically, the United States has been the global leader in biomedical research and innovation. Many factors have contributed to American dominance. For example, the National Institutes of Health (NIH) is the largest public funder of biomedical research in the world, many academic institutions in the United States attract top scientific talent and are among the best-rated institutions in the world for biomedical research, and the pharmaceutical and biotechnology industries have a large presence in the United States.

The Trump Administration, however, is actively undermining American leadership in science, innovation, and drug development. It is no exaggeration to say that Trump's actions today are ripping away the cures of tomorrow. Trump has allowed Robert F. Kennedy, Jr. and his sycophants to wreak havoc on the nation's core scientific infrastructure. The CBO recently found that a ten percent cut to NIH funding—an amount that is much smaller than the Trump Administration's cuts—would result in 53 fewer new drugs approved for patients.[118] Further, an estimated 74,000 patients enrolled in clinical trials were affected by Trump's NIH cuts between February 28th and August 15th, 2025 alone, causing patients to lose access to treatment for cancer and other diseases and disrupting progress toward finding and developing cures.[119]

Senate Democrats are interested in feedback about how we can bolster and invest in biopharmaceutical innovation. We are specifically interested in how Congress can spur more basic research, translational research, and clinical trials in areas of unmet need. We are also interested in advancing policies that will maintain American global dominance in biomedical innovation, especially in light of the recent growth in China's biopharmaceutical sector.

I. Enhancing Investments in Drug Research & Development

Drug discovery and development in the United States is a lengthy, multi-stage process supported by a robust innovation ecosystem. In this ecosystem, public and private stakeholders coordinate to share in the risk of developing drugs and ultimately bring medicines from "bench to bedside." The process often starts through publicly-funded basic research at universities or academic medical centers. Foundational scientific discoveries made in these contexts then sometimes proceed to clinical trials and ultimately may get FDA approval for marketing thanks to research conducted primarily by private sector companies, such as small biotechnology firms and larger pharmaceutical manufacturers.

The drug development process is lengthy, expensive, and risky. Drug development as a whole takes an average of 10 to 15 years and may cost hundreds of millions—or even billions—of

[118] Phillip L. Swagel to Ranking Members Jeff Merkley, Bernie Sanders, Frank Pallone, Jr., and Brendan Boyle, "How Changes to Funding for the NIH and Changes in the FDA's Review Times Would Affect the Development of New Drugs," Congressional Budget Office, July 18, 2025, https://www.cbo.gov/system/files/2025-07/61373-Drugs.pdf
[119] Vishal R. Patel et al., "Clinical trials affected by research grant terminations at the National Institutes of Health," *JAMA Internal Medicine* 186, no. 1 (2025): 126-128, https://doi.org/10.1001/jamainternmed.2025.6088

dollars.[120] The failure rate for drug candidates that have already advanced to clinical trials in the United States is approximately 90 percent.[121] NIH has noted that 80 to 90 percent of projects never even move beyond the preclinical phase.[122]

Senate Democrats request feedback and proposals on how to use levers in the Finance Committee's jurisdiction to support meaningful biopharmaceutical innovation and drug development within the United States. Specifically, we request feedback on how to support basic research, translational research, and clinical trials in a manner that is likely to lead to new cures and treatments in areas of unmet clinical need. We are also interested in feedback about how to help bridge what's known as the "valley of death": the expansive gap between basic research and successful clinical trials, and support high-risk science.

Basic Research

During the basic scientific research phase, scientists study diseases and research biological targets. NIH has historically been the world's preeminent funder of basic biomedical research, which contributes very significantly to the identification of compounds that pharmaceutical manufacturers ultimately develop into drugs. For example, a study analyzing 210 drugs approved between 2010 and 2016 found that all of the drugs had some connection to NIH research, with 90 percent linked to basic research funded by NIH and up to 30 percent having direct NIH contributions to the drug itself.[123]

The vast majority of NIH grants are carried out by universities and academic medical centers. As a result, academic institutions play a vital role in basic research that likely could not be replicated by the private sector, which has a different incentive structure and would not be able to tolerate the high risks and long timelines associated with most basic research. NIH funding is also critical in helping universities and academic medical centers recruit scientific talent, which helps maintain American dominance in biomedical innovation on the global stage. NIH funding supports approximately 370,000 jobs annually in the United States.[124] It often heavily influences an institution's research capacity, ability to support trainees, and how many labs it can operate.[125]

The Trump Administration's attacks on the NIH and academic institutions are catastrophic for long-term drug development and American global competitiveness on biomedical innovation. In

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[120] Izumi V. Hinkson, "Accelerating Therapeutics for Opportunities in Medicine: A Paradigm Shift in Drug Discovery," *Frontiers in Pharmacology* 11, no. 770 (2020), https://doi.org/10.3389/fphar.2020.00770; Andrew Mulcahy et al., "Use of Clinical Trial Characteristics to Estimate Costs of New Drug Development," *JAMA Open Network* 8, no. 1 (2025): e2453275, https://doi.org/10.1001/jamanetworkopen.2024.53275

[121] Helen Dowden and Jamie Munro, "Trends in clinical success rates and therapeutic focus," *Nature Reviews Drug Discovery* 18, no. 7 (2019): 495-496, https://doi.org/10.1038/d41573-019-00074-z

[122] "NIH Announces New Program to Develop Therapeutics for Rare and Neglected Diseases," National Institutes of Health, May 20, 2009, https://www.genome.gov/27531962/2009-release-nih-announces-new-program-to-develop-therapeutics-for-rare-and-neglected-diseases

[123] Ekaterina Galkina Cleary et al., "Contribution of NIH funding to new drug approvals 2010-2016," *Proceedings of the National Academy of Sciences of the United States of America* 155, no. 10 (2018): 2329-2334, https://doi.org/10.1073/pnas.1715368115

[124] Sandra Barbosu and Sarina Fereydooni, "How NIH-Funded Science Supports US Biopharmaceutical Innovation," Center for Life Sciences Innovation, December 15, 2025, https://itif.org/publications/2025/12/15/how-nih-funded-science-supports-us-biopharmaceutical-innovation/

[125] Marcy Gallo and Kavya Sekar, "NIH Indirect Costs Policy for Research Grants: Recent Developments," Congressional Research Service, April 17, 2026, https://www.congress.gov/crs-product/IN12516

2025, NIH issued 24 percent fewer grants.[126] As a result, scientists have been forced to delay, scale back, and abandon numerous experiments and projects studying fatal and debilitating illnesses. Specific examples of NIH cuts include a $202 million (19 percent) reduction in grant funding for cancer research, a $194 million (26 percent) reduction in grant funding for neurological disorder and stroke research, a $156 million (17 percent) reduction in grant funding for heart, lung and blood research, and a $50 million (37 percent) reduction in grant funding for research into the human genome.[127]

Ensuring robust government funding for basic research is vital to maintaining global competitiveness on biomedical innovation and making new discoveries that can ultimately be commercialized and benefit patients. **Senate Democrats therefore request feedback on how to bolster funding for basic scientific research in the United States.** Specifically, how to increase the production of basic research; help academic institutions and providers engage in more basic research and recruit more scientific talent; and increase the amount of basic research that is replicable. Because the pharmaceutical industry is the primary financial beneficiary of basic research conducted by NIH, what type of new funding stream could Congress create to fund NIH research through a new assessment on industry?

Translational Research

Based on discoveries from basic research, scientists and manufacturers may explore compounds further and ultimately run the clinical trials necessary to receive FDA approval to market a new drug. Unfortunately, many promising basic research discoveries that could result in potential drugs fail to become actual treatments. The gap between promising basic research and reaching human clinical trials is referred to in the pharmaceutical industry as the "valley of death." Many factors contribute to discoveries getting caught in the valley of death, including inefficient communication between academics and pharmaceutical manufacturers, promising early-stage projects still carrying too much risk for private investment, and the non-replicable nature of many basic research projects.[128]

Increased investments in translational research could help bridge the valley of death and convert promising discoveries into new treatments. "Translational research" refers to scientific research that is intended to bridge the gap between basic research and clinical trials. NIH's National Center for Advancing Translational Sciences (NCATS) is expressly dedicated to translational research and has a budget of around $1 billion annually.[129] Since its founding in December 2011, NCATS has already facilitated commercialization of at least three drugs: Agamree (for Duchenne Muscular Dystrophy), Kebilidi (for AADC deficiency), and Vivjoa (for vaginal yeast

[126] Max Kozlov et al., "U.S. Science After A Year of Trump," *Nature,* January 22, 2026, 812-815, http://nature.com/immersive/d41586-026-00088-9/assets/pdf/d41586-026-00088-9.pdf

[127] Aatish Bhatia et al., "The U.S. Is Funding Fewer Grants in Every Area of Science and Medicine," *The New York Times*, December 2, 2025, https://www.nytimes.com/interactive/2025/12/02/upshot/trump-science-funding-cuts.html

[128] Maaike Everts and Mark Drew, "Successfully navigating the valley of death: the importance of accelerators to support academic drug discovery and development," *Expert Opinion on Drug Discovery* 19, no. 2 (2024): 253-258, https://doi.org/10.1080/17460441.2023.2284824; Attila A. Seyhan, "Lost in translation: the valley of death across preclinical and clinical divide – identification of problems and overcoming obstacles," *Translational Medicine Communications* 4, no. 18 (2019), https://doi.org/10.1186/s41231-019-0050-7

[129] "Budget Overview," National Center for Advancing Translational Sciences, last modified April 17, 2026, https://ncats.nih.gov/about/budget

infections).[130] Other centers within NIH also carry out translational research within their specific disease areas. Historically, NIH investments in basic research have dwarfed translational research investments. For example, one study found that between 2010 and 2019, 83 percent of NIH grants were for basic research while only 17 percent went toward translational research.[131]

Senate Democrats request feedback on ways to to increase domestic investments in translational research. We request proposals that would encourage more translational research from academic institutions and other entities, as well as proposals that would create new funding streams for translational research at NIH.

In recent years, drug development "accelerators" have also emerged to try to overcome the valley of death. Accelerators are programs or organizations that provide funding, resources, lab infrastructure, industry partnerships, and technical expertise to scientists that make promising basic research discoveries to help support and speed-up commercialization.[132] They exist in academia (e.g., Harvard's Blavatnik Biomedical Accelerator, Stanford's SPARK, Vanderbilt's Warren Center for Neuroscience Drug Discovery) and as non-profits or venture philanthropy programs (e.g., Critical Path Institute's Translational Therapeutics Accelerator, Blood Cancer United's Therapy Acceleration Program). Stanford's SPARK, for example, funded translational research for two Stanford professors that ultimately led to the FDA approval of Attruby, a drug that treats a rare cardiac condition.[133] Blood Cancer United's Therapy Acceleration Program has funded translational research that led to multiple drug approvals, including for Komzifti (where the nonprofit specifically introduced the university scientists who conducted the basic research for the drug to the biotechnology company that commercialized it) and Elzonris.[134] Accelerators may also be backed by venture capital firms (e.g., Flagship Pioneering, IndieBio, Third Rock Ventures) or the pharmaceutical industry (e.g., Pfizer Breakthrough Change Accelerator, Johnson & Johnson Innovation, Lilly Gateway Labs). Current accelerators, however, have insufficient resources to explore all promising basic research discoveries. Much more work also needs to be done to connect scientists to accelerators or other entities that could help determine whether a discovery is "druggable."[135]

Senate Democrats request feedback and proposals to help stand-up or build upon effective biopharmaceutical accelerators. How should a "biopharmaceutical accelerator" be defined? What standards should accelerators have to meet and/or types of research should accelerators be supporting? Should policy address academic institutions and non-profit entities differently from venture capital firms and the pharmaceutical industry?

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[130] "NCATS Enables IND Clearances and Drug Approvals," National Center for Advancing Translational Sciences, last modified May 29, 2026, https://ncats.nih.gov/research/our-impact/our-impact-drug-discovery-and-development/drug-approvals
[131] Peter J. Pitts, "It's time to rethink, recalibrate, and redistribute NIH Funding," *Journal of the Academy of Public Health*, April 15, 2025, https://doi.org/10.70542/rcj-japh-art-1yh5z28
[132] Everts and Drew, "Navigating the valley of death."
[133] "FDA approves drug developed through SPARK," SPARK at Stanford, November 25, 2024, https://sparkmed.stanford.edu/fda-approves-drug-developed-through-spark/
[134] "Therapy Acceleration Program® (TAP)," Blood Cancer United, accessed June 8, 2026, https://bloodcancerunited.org/research/therapy-acceleration-program-tap
[135] Everts and Drew, "Navigating the valley of death."

Clinical Trials

Pharmaceutical manufacturers conduct clinical trials to develop drug candidates studied in basic and translational research into commercialized medicines that treat and cure patients. Under this process, a manufacturer sponsor submits an Investigational New Drug (IND) application to the FDA to initiate human testing. If approved, manufacturers may begin conducting smaller Phase I trials that study a drug candidate's safety as well as its pharmaceutical properties, such as how the drug is absorbed and cleared and what dosing is appropriate. Drug candidates can then proceed to Phase II trials, which begin to study efficacy amongst patients who have the disease or condition the drug candidate is intended to treat. Larger Phase III trials that often involve hundreds, if not thousands, of patients and study the drug candidate for safety and efficacy.

While drug development and the clinical trial process is a long-term, high-risk endeavor in general, some therapeutic areas and product types are associated with even higher risks. This is especially true for disease states and conditions where biology is poorly understood, clinical trials are expensive or long, or where products are difficult to commercialize with sufficient returns on investment. Unmet patient needs in these areas are often high. For example, neurodegenerative diseases (e.g., Alzheimer's disease, ALS, and Parkinson's disease) are often viewed as high-risk due to high clinical trial failure rates, complex disease biology, and costly, long clinical trials.[136] Other high-risk therapeutic areas for investment may include psychiatric conditions, certain autoimmune diseases, ultra-rare diseases and conditions, and antibiotics. Diseases that disproportionately or exclusively affect women have also long been an area of underinvestment.[137] Investing in cell and gene therapies may also be considered risky due to high manufacturing costs, commercial unpredictability, and other factors.[138]

Economic incentives to invest in certain types of medicines that would benefit large populations and focus on prevention may also be lacking. Some of these areas may include early-stage hypertension and cardiovascular disease prevention, vaccines, smoking cessation, and early metabolic disease prevention. Developing these "population health" drugs generally requires long and expensive clinical trials even though the ultimate per patient price point might be relatively low. In some cases, clinical trials may take so long that patent rights and exclusivities could be near expiration by time a drug gets marketed, which limits return on investment.[139] A recent OECD analysis found that R&D in these areas is underrepresented relative to oncology and chronic high-margin diseases.[140]

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[136] Rebecca Craven, "The risky business of drug development in neurology," *The Lancet Neurology* 10, no. 2 (2011): 116-117, https://www.thelancet.com/journals/laneur/article/PIIS1474-4422%2811%2970004-7/fulltext; Samantha Schumm et al., eds., "Factors Contributing to Misalignment Between Investment Priorities and Unmet Need," in *Aligning Investments in Therapeutic Development with Therapeutic Need: Closing the Gap* (National Academies Press, 2025), https://www.ncbi.nlm.nih.gov/books/NBK619076/

[137] Bridget Balch, "Why we know so little about women's health," *AAMC*, March 26, 2024, https://www.aamc.org/news/why-we-know-so-little-about-women-s-health

[138] Manfred Seow, "Navigating Funding Challenges in Cell and Gene Therapy Development," *IQVIA*, May 14, 2025, https://www.iqvia.com/locations/asia-pacific/blogs/2025/05/navigating-funding-challenges-in-cell-and-gene-therapy-development

[139] Eric Budish et al., "Do firms underinvest in long-term research? Evidence from cancer clinical trials," *American Economic Review* 105, no. 7 (2015): 2044-2085, https://doi.org/10.1257/aer.20131176

[140] "Health at a Glance 2025," OECD, November 13, 2025, https://www.oecd.org/en/publications/health-at-a-glance-2025_8f9e3f98-en/full-report/pharmaceutical-knowledge-and-innovation_4676acd0.html; "Pharmaceutical Innovation and Access to Medicines," OECD, November 29, 2018, https://www.oecd.org/en/publications/pharmaceutical-innovation-and-access-to-medicines_9789264307391-en/full-report.html

Senate Democrats request feedback on whether Congress should design policies to invest in developing drugs in specific therapeutic areas, such as disease states and conditions that are considered high-risk for drug development, where there are significant unmet clinical needs, or where there could be profound benefits for population health. How should such policies be structured, and what type of additional requirements (e.g. limited patent rights) would curb anticompetitive or price gouging behavior?

In many cases, smaller biotechnology companies have better incentives to engage in high-risk science and early clinical trials involving uncertain biology and novel modalities. Many smaller firms are funded by venture capital firms specifically to study a certain concept or hypothesis. Thus, rewards for smaller biotechnology companies come from succeeding in a particular area. Larger pharmaceutical companies may be less willing to take these risks until the science is more validated since they need to secure predictable quarterly returns for shareholders and manage diversified portfolios and pipelines. As a result, smaller biotechnology companies often contribute disproportionately to the development of novel mechanisms, while larger pharmaceutical companies contribute more to later-stage development and commercialization.[141]

There is already evidence that investing in small biotechnology firms can result in novel treatments for patients. For example, the NIH's Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs have a proven track record of spurring innovation. A 2022 National Academies study found that increases in SBIR/STTR funding led to "statistically significant increases in publications, patents, clinical trials, and drug approvals," which can lead to "reduced morbidity, mortality, hospitalization, costs, and…disease burden."[142] Between 1996 and 2020, firms involved in the SBIR/STTR programs developed 99 small-molecule and biologic drugs, which was more than 12 percent of all such drugs approved during this period.[143] Other countries, such as Canada and Australia, also offer refundable tax credits for R&D conducted by smaller companies.[144]

Senate Democrats request feedback and proposals on how to support high-risk science conducted by small biotechnology firms. If such policies were in place, what types of companies would be within scope, and should it vary for different points in the business life cycle (e.g., pre-revenue or revenue generating)?

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[141] Kate Kennedy et al., "Small biotechs versus large pharma: Who drives first-in-class innovation in oncology?" *Drug Discovery Today* 28, no. 2 (2023), https://doi.org/10.1016/j.drudis.2022.103456; Yusuke Izumiya et al., "Evolution of the division of labor for First-in-Class Drugs: A Quantitative Analysis of Trends across Company Types, Modalities, and Therapeutic Areas (2012–2024)," *Drug Discovery Today* 31, no. 3 (2026), https://www.sciencedirect.com/science/article/abs/pii/S1359644626000747; Joshua Krieger et al., "Missing Novelty in Drug Development," Review of Financial Studies 35, no. 2 (2022): 636–679, https://www.hbs.edu/faculty/Pages/item.aspx?num=60288&

[142] "Impact of the NIH SBIR/STTR Programs" in *Assessment of the SBIR and STTR Programs at the National Institutes of Health* (National Academies of Sciences, Engineering, and Medicine, 2022), 147, https://doi.org/10.17226/26376.

[143] National Academies, "Impact of the NIH SBIR/STTR Programs," 147.

[144] "SR&ED tax credit program significantly enhanced as Bill C-15 passes," BDO Canada, April 14, 2026, https://www.bdo.ca/insights/sr-ed-program-enhancements-and-updates-draft-legislation-released; "Overview of the R&D Tax Incentive," Commonwealth of Australia, accessed June 8, 2026, https://business.gov.au/grants-and-programs/research-and-development-tax-incentive/overview-of-rd-tax-incentive

II. Addressing Competition from China

As the Trump Administration's anti-science agenda diminishes the United States' standing, China is rapidly becoming a dominant global player in biomedical innovation. For example, China now accounts for nearly one-third of the global pharmaceutical R&D pipeline, a quarter of innovative drug candidates now under active development originate from China, nearly half of new drug molecules that entered human trials in the first half of 2025 were from Chinese companies, 31 percent of all newly registered clinical trials are in China, and China now accounts for approximately half of all global licensing deals by dollar value or 26 percent measured by deal volume.[145] Since 2020, the number of pipeline assets at the 100 most innovative Chinese biopharmaceutical companies has grown 100 percent, the number of patents they hold has grown 450 percent, and the number of clinical trials they were in the process of conducting has grown 110 percent.[146] These numbers are expected to rise further, and while Chinese companies currently account for only five percent of FDA approvals, the number is expected to jump to 35 percent by 2040.[147]

China makes substantial government-backed investments in biopharmaceutical R&D. The Chinese government has a series of long-term strategic plans to cultivate a centrally-coordinated innovation ecosystem. In 2015, China launched "Made in China 2025," which identified biotechnology and biopharmaceuticals as priority growth sectors. Since then, China has implemented several Five-Year Plans that lay out specific funding priorities and regulatory changes.[148] Pursuant to these plans, China is investing significant public funding in biopharmaceutical innovation and infrastructure development. China's total national R&D expenditures tripled between 2012 and 2022, and its government spending on R&D increased approximately 90 percent between 2013 and 2023.[149] By 2024, China's total national R&D spending surpassed the United States' and its public R&D spending is expected to do the same within the next three years.[150] For example, China launched numerous funds, including a Parent Fund and an M&A fund, which finance companies that are in late-stage clinical trials or are in the process of commercializing drugs.[151] China also has dozens of biotech hubs backed by

[145] Ian Lloyd, "Pharma R&D Annual Review 2025," Citeline, March 2025, https://www.citeline.com/en/rd25; "China Is Increasing Its Share of Global Drug Development," Goldman Sachs, December 17, 2025, https://www.goldmansachs.com/insights/articles/china-is-increasing-its-share-of-global-drug-development

[146] "Mainland China Biopharma Innovation 2.0," Clarivate, December 8, 2025, https://img06.en25.com/Web/ClarivateAnalytics/%7B3940d85a-73e6-4f5a-abb0-ca63d42749bd%7D_BXD1745169405_LS_H_China_Innovation_Top_100_Report_EN_09.pdf

[147] "The Innovation Boom in China Biotech," Morgan Stanley, September 10, 2025, https://www.morganstanley.com/insights/articles/china-biotech-boom-generics-to-innovators

[148] Laura Jochem, "Why China is becoming the top biopharma innovation hotspot," Oliver Wyman, May 2026, https://www.oliverwyman.com/our-expertise/perspectives/health/2026/may/china-hotspot-for-biopharma-innovation.html

[149] "China's R&D spending triples in past decade," The State Council Information Office of the People's Republic of China, May 16, 2023, http://english.scio.gov.cn/m/pressroom/2023-05/16/content_85335893.htm; Ben Deighton, "China could be the world's biggest public funder of science within two years," *Nature*, March 19, 2026, https://www.nature.com/articles/d41586-026-00618-5

[150] Matt Hourihan, "It's Official: China Tops U.S. in R&D Spending," Association of American Universities, March 31, 2026, https://www.aau.edu/newsroom/leading-research-universities-report/its-official-china-tops-us-rd-spending; Deighton, "China could be."

[151] Clarivate, "Mainland China Biopharma."; Alex Kesin, "China's leap in pharma: slow and fast trends behind its rise," *Alex Kesin's Pharmacopoeia*, February 21, 2025, https://www.alexkesin.com/p/chinas-leap-in-pharma-slow-and-fasthtml

government support, including direct funding, low or no-interest loans, free or discounted land, discounted utilities, and cash rebates for the construction of new manufacturing facilities.[152]

China's rise as a major player in drug development and biomedical innovation has wide-ranging implications for the United States—spanning economics, national security, public health, and scientific leadership. **Senate Democrats are interested in policy ideas that will help maintain American dominance in biopharmaceutical innovation**. We are particularly interested in how Congress could drive U.S.-based pharmaceutical innovation and research, increases in clinical trial participation and efficiency, and recruitment and cultivation of scientific talent.

Boosting Domestic Clinical Trials

Conducting clinical trials in China is often faster and less expensive than in the United States due to lower labor costs, streamlined regulatory processes, and simplified patient recruitment.[153] China can enroll patients in clinical trials two to five times faster than the United States due to its large population and centralized hospital system. Clinical trials can cost 50 to 60 percent less in China than the United States due to these types of efficiencies, as well as a streamlined regulatory process and lower per patient costs.[154] These factors and others have contributed to significant growth in clinical trials in China. Annual Phase I clinical trials in China have grown ten-fold over the past decade.[155] In 2024, China listed more than 7,100 clinical trials, compared to approximately 6,000 in the United States.[156]

To remain competitive on the global stage, the United States should work to increase clinical trial efficiency while still preserving our rigorous review processes and vital patient protections. **Senate Democrats request feedback on ways to enhance efficiency, lower costs, and increase clinical trial participation**. For example, should we take steps to ensure that reimbursement or stipends to cover patient costs associated with clinical trial participation do not run afoul of Medicare, Medicaid, or program integrity laws? Could we find ways for more providers to become clinical trial sites, remove duplication in Institutional Review Board (IRB) processes, or otherwise make clinical trial enrollment more efficient and accessible?

Scientific Talent

China has also successfully mobilized scientific talent, including by producing its own vast biomedical workforce and by recruiting scientists from overseas.[157] For example, in the 1990s,

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[152] Kesin, "China's leap."; Robert D. Atkinson and Caleb Foote, "To Understand Chinese Innovation Success, Look No Further Than Government R&D Subsidies," Information Technology & Innovation Foundation, October 23, 2019, https://itif.org/publications/2019/10/23/understand-chinese-innovation-success-look-no-further-government-rd/; Anirudh Roy Popli et al., "The emerging epicenter: Asia's role in biopharma's future," McKinsey & Company, January 7, 2026, https://www.mckinsey.com/industries/life-sciences/our-insights/the-emerging-epicenter-asias-role-in-biopharmas-future

[153] Clarivate, "Mainland China Biopharma."; Popli, "The emerging epicenter."

[154] Will Maddox, "How RA Capital is offering its biotechs 'Chinese clinical expertise in a box,'" *Fierce Biotech*, June 5, 2026, https://www.fiercebiotech.com/biotech/how-ra-capital-offering-its-biotechs-chinese-clinical-expertise-box

[155] Chen Chen et al., "Trends of Phase I Clinical Trials of New Drugs in Mainland China Over the Past 10 Years (2011–2020)," *Frontiers in Medicine* 8 (2021), https://doi.org/10.3389/fmed.2021.777698

[156] Adriel Bettelheim and Maya Goldman, "China's biotech boom leaves U.S. playing catch-up," *Axios*, May 29, 2025, https://www.axios.com/2025/05/29/china-biotech-boom-us-drug-trials

[157] Kiki Han et al., "The dawn of China biopharma innovation," McKinsey & Company, October 29, 2021, https://www.mckinsey.com/industries/life-sciences/our-insights/the-dawn-of-china-biopharma-innovation#/

China began investing heavily in expanding STEM education, including in areas like chemistry and biotechnology. Project 211 and Project 985, both launched in the 1990s, invested heavily in creating elite research universities and helped fund labs, recruitment of elite faculty, and research infrastructure. In 2015, China also launched the Double First Class University Plan, which aims to develop qualifying universities into world class institutions, with a strong emphasis on research and global scientific competitiveness.[158] Due in part to these initiatives, university admission rates in China rose from 9.8 percent to over 48 percent between 1998 and 2018.[159] As of 2020, China graduated over 100,000 more STEM students with advanced degrees than the United States.[160]

China also deploys aggressive recruitment programs to keep scientists in China and bring them back from abroad. In recent years, China has launched over 200 talent recruitment programs targeting scientists.[161] For example, in 2008, China launched the Thousand Talents Plan to recruit top scientific talent. Under the plan, qualifying scientists are eligible to receive guaranteed lab funding and space, high salaries and signing bonuses, housing support, and other benefits. The program attracted thousands of scientists. However, other countries criticized the program due to researcher conflicts of interest and concerns about intellectual property theft.[162] Nevertheless, China continues to poach scientific talent from the United States. In September 2025, CNN reported that at least 85 American scientists moved to China since 2024, over half of whom had done so during Trump's second term.[163] Chinese recruitment materials emphasize Trump's crusade against science, medicine, and immigrants.[164]

The United States does not have a centrally-coordinated program focused on recruiting scientific talent. Rather, we rely on university funding, research grants from NIH and other entities, fellowship programs, and visa and green card programs for elite talent. **Senate Democrats request feedback on how the United States can do more to cultivate, recruit, and retain scientific talent domestically.**

Lessons from the Inflation Reduction Act and CHIPS and Science Act

As the Finance Committee designs policies to bolster American biopharmaceutical research and development against rising Chinese influence, two pieces of legislation show how well-designed, targeted incentives can lead to dramatic increases in innovation, manufacturing, and employment

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[158] Christine Chiu, "Project 211, Project 985, C9 League, and Double First Class," *China Admissions*, August 11, 2020, https://www.china-admissions.com/blog/guide-to-chinese-universities-project-211-project-985-c9-league/
[159] Can Cui et al., "The Interregional Migration of Human Capital: The Case of 'First-Class' University Graduates in China," *Applied Spatial Analysis and Policy* 15 (2022): 397-419, https://link.springer.com/article/10.1007/s12061-021-09401-7
[160] Jeremy Neufeld, "STEM Immigration Is Critical to American National Security," Institute for Progress, March 30, 2022, https://ifp.org/stem-immigration-is-critical-to-american-national-security/
[161] "Evaluating the Success of China's 'Young Thousand Talents' STEM Recruitment Program," Stanford Center on China's Economy and Institutions, 2023, https://sccei.fsi.stanford.edu/china-briefs/evaluating-success-chinas-young-thousand-talents-stem-recruitment-program
[162] Hepeng Jia, "China's plan to recruit talented researchers," *Nature*, January 17, 2018, https://www.nature.com/articles/d41586-018-00538-z; "The China Threat," FBI, accessed June 8, 2026, https://www.fbi.gov/investigate/counterintelligence/the-china-threat/chinese-talent-plans
[163] Simone McCarthy et al., "In the race to attract the world's smartest minds, China is gaining on the US," *CNN*, September 29, 2025, https://www.cnn.com/2025/09/29/china/china-reverse-brain-drain-science-tech-competition-us-intl-hnk
[164] "Abandoning the US: top Chinese scientists return home," *South China Morning Post*, November 18, 2025, https://www.scmp.com/news/china/series/3325286/abandoning-us-top-chinese-scientists-return-home?module=perpetual_scroll_0&pgtype=article

in the United States. The *Inflation Reduction Act* was meant to make the United States the global leader in industries such as electricity generation, clean manufacturing, and commercial, residential, and transportation decarbonization, while the *CHIPS and Science Act* was meant to boost domestic semiconductor manufacturing after a substantial share had shifted offshore. Each bill used a mix of tax incentives, loan guarantees, increases in research spending, and other policies to strengthen the United States' position in industries vital for our economic competitiveness against China.

After passage of both laws in the summer of 2022, domestic investment in manufacturing skyrocketed, with clean energy manufacturing, generation and storage, and semiconductors as the major drivers of this growth. By 2024, the United States hit record-highs in manufacturing investment, doubling what it had been just a few years prior.[165] These investments boosted domestic growth and innovation, and specifically in areas of major innovations where the United States and China were in direct competition to be leaders in the future.

Senate Democrats request feedback on how laws like the *Inflation Reduction Act* and the *CHIPS and Science Act* can inform efforts to boost domestic biopharmaceutical innovation. What types of approaches could be used to help biopharmaceutical startups and other early-stage companies innovate and grow? What fundamental differences between biopharmaceuticals and the semiconductor and energy industries should the Committee be aware of that could potentially influence how policies are structured? How would any relevant provisions need to be adapted to create effective incentives for biopharmaceutical innovation? In an industry with a history of shifting profits overseas while most patients and revenue are located in the United States, how would policies simultaneously make investments in spurring biopharmaceutical growth and address future tax avoidance when products become successful revenue generators?[166]

[165] Karen Dynan, "Investment in US factories has soared since the end of 2022," Peterson Institute for International Economics, May 1, 2024, https://www.piie.com/research/piie-charts/2024/investment-us-factories-has-soared-end-2022

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