

## [Drug Pricing Reform Proposals: Considerations for Cancer Care](#)

### Introduction

Drug therapies are the bedrock of cancer care. Making these therapies affordable, while continuing to encourage innovation of new treatments, is crucial to accomplishing the mission of the American Cancer Society Cancer Action Network (ACS CAN) to end cancer as we know it, for everyone. ACS CAN has long fought for public policies that support both the affordability and availability of medically necessary prescription drugs.

Congress and the Administration are moving forward with proposals to address drug pricing, from the enactment of the Inflation Reduction Act (IRA) to newly released Executive Orders (EOs). This paper provides an overview of some of these prescription drug pricing proposals and the potential impact on cancer care.

### Background

Prescription drug pricing has been a focus of Congress and both past and current presidential administrations. In 2022, Congress passed the IRA, giving Medicare authority for the first time to negotiate the price of prescription drugs directly. To date, five oncology drugs have been included in the first two rounds of negotiation, and it is anticipated that additional cancer drugs will be included in subsequent negotiations. More recently, the Trump Administration announced plans to further address drug pricing through the publication of two Executive Orders (EOs) – one directing federal agencies to lower drug costs for consumers through payment reforms and the other calling for the creation of a most-favored nation (MFN) program that would provide drugs to consumers at the lower prices paid for by other “favored” nations that have cost controls.

### Medicare Prescription Drug Negotiation

The IRA Medicare Drug Price Negotiation Program (Negotiation Program) is currently in the negotiation phase for the second cycle of drugs. This cohort includes fifteen Part D (pharmacy benefit) drugs, four of which are cancer-related treatments (Xtandi, Pomalyst, Ibrance, and Calquence). The Maximum Fair Prices (MFPs) for these products will be announced in November 2025 and take effect in 2027. This follows the first round of negotiations, which included ten Part D drugs whose MFPs will take effect in 2026. This first cohort included one cancer product, Imbruvica, which received an MFP that is 38% lower than its 2023 list price.<sup>1</sup>

At the same time, the Centers for Medicare & Medicaid Services (CMS) is preparing to negotiate the third cycle of drugs, which will be selected in early 2026, and for the first time will include Part B (medical benefit) drugs that will have MFPs effective in 2028.

On May 12, 2025, CMS published draft guidance for Initial Price Applicability Year (IPAY) 2028. The guidance outlines the renegotiation process for previously selected drugs and the selection and negotiation process for drugs payable under Part B. Additionally, the guidance offers more transparency into the selection process. For instance, the guidance provides examples of how the agency will determine if a product has “bona fide” generic or biosimilar competition (thereby making it ineligible for negotiation). The guidance also acknowledges the potential for insurers to change formulary placement and impose greater utilization management – potentially steering

beneficiaries towards or away from certain drugs. CMS indicates it will be monitoring these potential actions that could adversely impact beneficiaries.

CMS has also proposed publishing a list of up to 50 top negotiation-eligible drugs (ranked by total expenditures) when the next round of drugs selected for negotiation is announced. This differs from previous years, where CMS announced only the selected drugs.

Another issue related to the negotiation program is the change in how reimbursement will be calculated. CMS will base reimbursement on the Maximum Fair Price (MFP) plus six percent rather than the current Average Sales Price (ASP) plus six percent. This change will likely significantly reduce payment for Part B drugs – many of which are cancer therapies. Legislation introduced in 2023 in both the House and Senate seeks to provide a technical fix. The Protecting Patient Access to Cancer and Complex Therapies Act (S. 2764, H.R. 5391) - introduced by U.S. Senator John Barrasso (R-WY), U.S. Representative Michael Burgess (R-TX) and U.S. Representative Greg Murphy (R-NC), would maintain the current ASP+6 payment and direct drug manufacturers to rebate the Medicare program the difference between the ASP+6 rate and the new negotiated rate. Since Medicare beneficiary coinsurance would still be based on the lower negotiated rate, beneficiaries – including cancer patients – would realize savings.

In addition to establishing the Negotiation Program, the IRA also redesigned the Part D benefit to cap annual out-of-pocket costs for Medicare beneficiaries, in part by increasing plan liability. To mitigate this higher financial liability, plans proposed higher premiums for the 2025 plan year, and in response, the Biden Administration launched a voluntary Part D premium stabilization demonstration to cap premium increases for stand-alone Part D plans. The demonstration began in January 2025 and is structured to run for three years, although the Trump Administration may make changes to the model.

### *Potential Impact of Negotiation on Cancer Therapies*

Questions about the potential impact of government-set or negotiated prices on pharmaceutical research and development began before the enactment of the IRA. Studies that projected the effects of the Negotiation Program on pharmaceutical innovation varied widely, with the Congressional Budget Office (CBO) predicting the law would result in 13 fewer drugs coming to market over the next 30 years,<sup>2</sup> and other non-governmental analyses predicting 130 fewer drugs would be developed over the next 10 to 20 years.<sup>3</sup> For example, a University of Chicago study found that the IRA could lead to 79 fewer small-molecule drugs or 188 fewer indications.<sup>4</sup>

In addition to overarching concerns about fewer oncology drugs being developed, implementation of the IRA also raises questions about the extent to which negotiated prices will have an effect on manufacturers' long-term investment in certain types of research, including:

- Prioritizing the development of biological products over small molecules because of their longer time period before being eligible for selection;<sup>5</sup>
- Forgoing efforts to pursue additional indications for products currently eligible for the orphan exemption to the Negotiation Program, thereby reducing available treatment options for patients with rare cancers;<sup>1</sup>
- Prioritizing a product launch with an indication that encompasses a larger patient population, rather than launching sooner with a smaller patient population (resulting in fewer sales), to maximize revenue before being selected for negotiation; and

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<sup>1</sup> The Optimizing Research Progress Hope And New Cures Act (ORPHAN Cures Act) (H.R.946) was introduced to address this concern. The bill would expand the existing orphan exemption by allowing products with any number of rare indications and Food and Drug Administration (FDA) designations to qualify. This provision was ultimately included in the final reconciliation package (H.R. 1, formerly known as the “One Big Beautiful Bill Act”) that President Trump signed into law in July 2025).

- Prioritizing research and development focused on products that treat commercial or Medicaid patient populations over those likely to be enrolled in Medicare (note: this outcome may be more likely for companies that do not solely focus on oncology).<sup>2,6</sup>

Some manufacturers have spoken broadly about these dynamics, while other companies have made specific statements on the oncology impact, particularly around the prioritization of biologics and/or deprioritization of small molecules:

- **Pfizer:** Press reported that Pfizer leadership stated that the mix of small molecule drugs in its cancer portfolio will “plummet from 94% last year [2023] to 35% in 2030”.<sup>7</sup>
- **Genentech:** “There are many important small molecule therapeutics, particularly in cancer, and nine years isn’t enough for the amount of time it takes to get from a metastatic setting into the curative setting.”<sup>8</sup>
- **Eli Lilly:** ATI Advisory reported that Lilly discontinued a phase I cancer drug candidate and that the company pointed to the IRA’s treatment of small molecules as a key factor.<sup>9</sup>

Given that the IRA has only been law for three years and the first round of negotiated prices has yet to take effect, it’s still unclear how the Negotiation Program will impact beneficiaries or the development of small molecule drugs long term. Early research is mixed, with some studies suggesting innovation concerns are coming to fruition. A study of clinical trials post-IRA passage found that the initiation of post-approval studies decreased substantially for large molecule drugs (a 32.9% decrease) and even more for small molecule drugs (a 47.3% decrease).<sup>10</sup> Similarly, an assessment of venture capital investments in large and small molecule assets focused on Medicare-aged populations found that investments declined by a median of 74%, with investments in specific cancer indications (e.g., gastric and prostate cancer) exceeding that amount.<sup>11</sup> However, an analysis of mergers and acquisitions found that investment in small molecules grew at a faster rate after the passage of the IRA, suggesting the law may not be significantly hindering small molecule innovation.<sup>12</sup>

## Executive Orders (EOs)

The recent EOs build on policies from the first Trump Administration, proposing changes to importation policy, reimbursement structures, and international pricing practices, among other notable provisions. The EOs do not carry the force of law, are largely directional, and contain few details on what specific reforms may be implemented to support the directives. Still, early details and past proposals indicate potential policy scenarios that the Administration and Congress may pursue.

### [The “Lowering Drug Prices by Once Again Putting Americans First” Executive Order](#)

Announced April 15, 2025, the Lowering Drug Prices EO includes several provisions and outlines actions federal agencies should take to achieve lower drug prices for patients, including proposals focused on drug payment reform, examining anti-competitive behavior by industry stakeholders, accelerating the approval of lower-cost generics and biosimilars, and shifting patient care to less expensive settings.<sup>13</sup>

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<sup>2</sup> The passage of budget reconciliation bill H.R. 1 includes severe cuts to Medicaid and changes to Marketplace plans, which are projected to result in nearly 10 million losing health coverage. Error! Bookmark not defined. Any potential shift by manufacturers to prioritize development for commercial and Medicaid patient populations does not account for the significant coverage losses that would result from H.R. 1.

Specifically, the EO directs federal agencies to: 1) release guidance for the Negotiation Program intended to improve transparency, prioritize the selection of high-cost Medicare drugs, and minimize negative impacts on innovation; 2) work with Congress to align small molecule drug eligibility for negotiation with biological product eligibility; and 3) provide recommendations on how to stabilize and reduce Medicare Part D premiums. Provisions of the EO include:

**Improving upon the IRA:** This provision directs an end to what is called the “pill penalty,” eliminating the disadvantage that makes small molecule drugs eligible for the Negotiation Program four years earlier than biological products. The EO describes how this discrepancy threatens to distort innovation by pushing investment toward more expensive biological products that treat rarer diseases and away from generally cheaper small molecules that treat larger patient populations. This directive would require legislative change and could be pursued through the Ensuring Pathways to Innovative Cures (EPIC) Act of 2025,<sup>14</sup> which would align small molecule selection with that for biologics.

Recommendations focused on stabilizing and reducing Part D premiums could include near-term modifications to the Part D premium stabilization demonstration for the remaining years in the model or more permanent changes to the Part D program through legislation.

Equally important to access and affordable treatments is the investment in research and development of novel, advanced therapies that may increase survival and ultimately cure cancers. The EO directs guidance be implemented to minimize the negative effects of negotiation on innovation, and second, calls for the alignment of small molecule and biological product negotiation eligibility.

**Reducing the Prices of High-Cost Drugs for Seniors:** This EO provision calls for the establishment of a Medicare value-based payment model within one year for high-cost prescription drugs and biologicals, including those not currently subject to IRA provisions. The CMS Innovation Center, which announced a refreshed strategy aligned with Making America Healthy Again (MAHA) priorities on May 13, 2025, would implement the model.<sup>15</sup> The Innovation Center has implemented few drug-focused models in Medicare to date, the most notable being the Part D Senior Savings Model, which reduced copays for certain insulin products before a similar requirement was enacted into law as part of the IRA. In Medicaid, the Cell and Gene Therapy Access Model for sickle cell disease is underway. A Medicare model focused on high-cost drugs for seniors may mirror or build on either of these models.

**Appropriately Accounting for Acquisition Costs of Drugs in Medicare:** This provision requires a survey to determine hospital acquisition costs for covered outpatient drugs at hospital outpatient departments (HOPDS) and the proposal of any appropriate adjustments to align Medicare payment with the cost of acquisition. In the 340B program, certain hospitals can purchase drugs at discounted prices, and Medicare pays the same rate for drugs regardless of the acquisition cost. From 2018 to 2022, CMS lowered physician-administered drug payments for 340B drugs to better align with acquisition costs<sup>16</sup>, but a Supreme Court ruling (*American Hospital Association et al. v Becerra*) overturned this policy because the agency failed to conduct a cost survey. This EO provision may result in an acquisition cost survey followed by a similar proposal to lower payment rates to better align with drug acquisition costs. Because beneficiary financial liability is linked to Medicare reimbursement, such a policy may lower patient costs.

**Promoting Innovation, Value, and Enhanced Oversight in Medicaid Drug Payment:** The EO calls for recommendations on how to: 1) best ensure that manufacturers pay accurate Medicaid drug rebates, 2) promote innovation in Medicaid drug payment methodologies, 3) link payments for drugs to the value obtained, and 4) support states in managing drug spending. This provision is more ambiguous than others in the EO, and the recommendations could address several aspects of Medicaid drug payment. Some possible reforms include

improvements to manufacturer-reported pricing and classification data to capture lost Medicaid rebates, as detailed in a 2017 Office of Inspector General (OIG) report<sup>17</sup>, the permission of more advanced value-based payment models that include additional risk components, or the allowance of closed formularies.

**Reevaluating the Role of Middlemen:** This provision calls for recommendations on promoting a “more competitive, transparent, and resilient” pharmaceutical value chain that lowers drug prices. Recommendations are likely to target the contracting structure and anticompetitive practices of Pharmacy Benefit Managers (PBMs), ranging from directing the Federal Trade Commission (FTC) to take action against PBM monopolies and perverse incentives associated with vertical integration to supporting Congressional “delinking” policies, which would restructure PBM contracting by requiring compensation to be flat service fees instead of arrangements based on drug prices.

**Accelerating Competition for High-Cost Prescription Drugs:** The EO directs the FDA Commissioner to issue a report with recommendations on how to 1) accelerate the approval of generics, biosimilars, and other competitive products and 2) improve the over-the-counter reclassification process and identify prescription drugs that can be safely provided over the counter. FDA Commissioner Makary highlighted several priorities in his confirmation hearing that align with these directives, including changes to FDA Orange Book patent listings and oversight, easier or faster pathways for generic and biosimilar approvals, and new processes to reclassify certain prescription drugs as over-the-counter.<sup>18</sup> While Commissioner Makary did not provide specifics on these proposals, he noted their overall impact would be to lower costs for patients.

**Increasing Prescription Drug Importation to Lower Prices:** The EO also directs the FDA Commissioner to streamline and improve the drug importation program. To date, only one state’s importation program (Florida) has been approved, but it has not yet been implemented, and a handful of other states have either submitted importation proposals or passed importation legislation.<sup>19</sup> The program requires substantial state effort to test and monitor imports and a willing international partner. Some countries have stated they will not participate in an American importation program, and more countries may be unwilling given the Administration’s tariff policies. While a streamlined program may relax some of these requirements, importation is unlikely to substantially impact patient costs without broad state interest and implementation.

**Reducing Costly Care for Seniors:** Under this provision, the Department of Health and Human Services (HHS) Secretary would propose regulations to ensure Medicare payment does not incentivize drug administration in more expensive sites of care (e.g., HOPD versus physician office). These regulations are likely to propose reduced payments for HOPDs for drug administration services, potentially resulting in lower patient cost-sharing.<sup>20</sup>

**Improving Transparency into Pharmacy Benefit Manager Fee Disclosure:** The EO directs the Secretary of Labor to propose regulations to improve employer health plan fiduciary transparency into the direct and indirect compensation received by PBMs. These regulations are likely to propose transparency requirements for PBMs to provide employer health plan sponsors with more information when making benefit decisions on behalf of their employees. However, legislation would be required to make more substantial changes (e.g., subjecting PBMs to fiduciary duties, which would require them to act in the best interest of plan participants and keep costs low).

**Combating Anti-Competitive Behavior by Prescription Drug Manufacturers:** The EO calls for the HHS Secretary to work with the Departments of Justice and Commerce and the FTC to issue recommendations on reducing anti-competitive behavior from pharmaceutical manufacturers. The recommendations may address manipulation of the patent system and other actions viewed as “gaming” to prevent competition in the market.

## Potential Impact of the Lowering Prices EO for Cancer Patients

While the *Lowering Drug Prices by Once Again Putting Americans First EO* signals a strong commitment to lowering drug prices and improving system-wide transparency, it also raises important questions for cancer patients and the future of oncology innovation.

**Site-Neutrality:** To comply with the EO, HHS is likely to propose site-neutral payment regulations for HOPDs. Establishing site-neutral payments has a high potential to reduce spending for patients and Medicare, especially impacting patients requiring high-cost services.<sup>21</sup> A 2023 study found that aligning reimbursement for drug administration services between off-campus HOPDs and freestanding physician services would have reduced cost sharing for traditional Medicare beneficiaries by about \$1 on average in 2021 but by \$1,055 among beneficiaries with the greatest use of chemotherapy who receive care at off-campus HOPDs that are not subject to existing site-neutral reforms (in addition to reducing the standard Part B premium by about \$1).<sup>22</sup>

Site-neutral payment proposals for HOPDs can be a positive move for cancer patients provided that the carve-out for Prospective Payment System (PPS)-exempt dedicated cancer centers included in the Bipartisan Budget Act of 2015 is retained. Maintaining this exemption recognizes the unique services provided by cancer centers, particularly for patients who require complex care.

**Acquisition Cost-Based Hospital Payments:** After conducting a survey of acquisition costs, HHS may lower drug reimbursement for 340B hospitals. Previous changes to Part B reimbursement for drugs furnished by 340B hospitals lowered Medicare program costs, as well as patient costs, as beneficiary cost-sharing is linked to Medicare payments. Specifically, between 2018 and 2022, Medicare adjusted the payment rate for 340B drugs to ASP minus 22.5% to reflect hospital acquisition costs more accurately. Though this change was ultimately rescinded, the policy continues to be recommended by the Medicare Payment Advisory Commission (MedPAC) due to the substantial savings. A recent MedPAC analysis estimated that Medicare and beneficiaries' payments in 2022 exceeded acquisition costs by approximately 48% overall, and 42% for cancer products specifically.<sup>23</sup>

The 340B program's financial incentives encourage hospitals to use costlier medications – increasing the amount that cancer patients pay in cost sharing – and contribute to consolidation of cancer care within the hospital setting. Policies that realign the financial incentives associated with the 340B program, ensure access to community care, and avoid extra out-of-pocket costs would benefit cancer patients.

**Generic, Biosimilar, and OTC Reform:** Introduction of biosimilars and generics to the market decreases drug prices by increasing competition, and generic and biosimilar treatments for cancer save patients and the overall health system \$25.5 billion annually.<sup>24</sup> A recent study found that the introduction of a generic or biosimilar was associated with a 51% reduction in annual spending in the two years following the approval.<sup>25</sup> Accelerating the generic and biosimilar approval process, as the EO directs, may increase these savings by providing more rapid access.

Generics and biosimilars play an important role in cancer treatment by providing a more affordable alternative to brand drugs and biologics, respectively. Expanding access to biosimilar and generic drugs – including incentivizing greater uptake of biosimilars by reducing patient cost sharing for cancer patients – can reduce the overall cost of cancer care for patients.

**PBM Disclosures:** PBMs often operate with opaque business practices and strongly influence prescription drug coverage and reimbursement. A recent FTC report found that the “Big 3” PBMs marked up two specialty generic cancer drugs (imatinib and abiraterone) by several thousand percent and then paid their affiliated pharmacies

hundreds of millions of dollars more than estimated acquisition costs in dispensing revenue for each drug annually.<sup>26</sup> Increased fiduciary transparency can provide plan sponsors with additional information regarding drug pricing, allowing for more informed decision-making when entering PBM contracts. However, the impact on patient costs will likely vary depending on what action (or lack thereof) the plan sponsor takes. Other proposed PBM reforms, such as requiring PBMs to share savings obtained from manufacturer-provided rebates with patients, are likely to have a more direct impact on reducing costs for cancer patients.

Any PBM reforms – including improving transparency – should ensure patients directly benefit from the resulting cost savings, making treatment more affordable for cancer patients.

**Drug Importation:** While many brand-name cancer drugs are significantly cheaper in Canada, under the drug importation program, there are significant concerns about patient safety. An FDA report revealed that 85% of medicines purchased from “Canadian” Internet pharmacies are “falsely promoted as being of Canadian origin.”<sup>27</sup>

Should the EO’s drug importation provisions take effect, the FDA would need to strengthen monitoring, testing, and oversight requirements. Protecting the safety and efficacy of the U.S. prescription drug supply must take precedence over savings that may never be realized. As written, this provision raises many questions about patient safety, administrative feasibility, and actual savings for consumers.

**Value-Based Payment Models:** A CMS Innovation Center model for high-cost Medicare products and value-based Medicaid reforms has the potential to reduce drug costs for beneficiaries as outlined in the EO. However, no single oncology drug is medically appropriate to treat all cancers. These products often have different indications, different mechanisms of action, and different side effects – all of which need to be managed to fit the medical needs of each individual.

Certain scenarios may substantially restrict a physician’s ability to prescribe the most medically appropriate treatment. For example, if a Medicare model only applies to certain cancer products, it would be challenging to establish low-cost sharing for some but not all cancer products. In that case, oncologists may be obliged to prescribe the more affordable medicine over the most appropriate one. Similarly, if innovative Medicaid arrangements restrict coverage to certain products, providers and patients may be subject to a lengthy appeals process to access the right medicine. It is essential to balance the impact of value-based payment models with treatment innovations based on personalized medicine and issues related to side effects and drug interactions. New value-based models would need to be carefully implemented to avoid unintended consequences for patient access to oncology products.

### **The “Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients” Executive Order**

Announced May 12, 2025, the MFN EO calls for the Commerce Secretary and the U.S. Trade Representative to take action against countries that “suppress the price of [drugs] below fair market value”, the HHS Secretary to facilitate direct-to-consumer (DTC) purchasing programs at MFN prices, and for American patients to have access to drugs at MFN target prices. HHS later defined MFN target prices as the lowest price a drug is sold for in an Organization for Economic Co-operation and Development (OECD) member country with a GDP per capita of at least 60% of the U.S. GDP per capita.<sup>28</sup> In addition to the EO, multiple MFN-related drug pricing proposals are currently under discussion in Congress. Provisions of the EO include:

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**Addressing Foreign Nations Freeloading on American-Financed Innovation:** The EO calls for the Commerce Secretary and the U.S. Trade Representative to prohibit foreign countries from suppressing the price of pharmaceutical products below fair market value. Actions against foreign countries may include additional tariffs or trade prohibitions. In a May 22, 2025, press event, President Trump indicated that one avenue would be to restrict the sale of foreign goods into the U.S. (e.g., cars, alcohol).

**Enabling DTC Sales to American Patients at the MFN Price:** The EO directs the HHS Secretary to facilitate DTC purchasing programs for pharmaceutical manufacturers that sell products at the MFN price. Details on what DTC purchasing programs for MFN-priced products would look like are unclear including how the program would be implemented for physician-administered drugs. Products offered at an MFN price may result in lower patient costs, but this will likely vary depending on the specific product and the individual patient's existing drug coverage. For example, a DTC purchasing program for MFN prices may lower costs for the uninsured, but not for a patient enrolled in a plan that covers a given product with limited out-of-pocket costs.

**Establishing MFN Pricing:** The EO also directs the Administration to set MFN price targets, and if "significant progress" toward the targets is not delivered, calls for 1) the imposition of MFN pricing via rulemaking, 2) the allowance of drug importation from developed nations, 3) enforcement action against anti-competitive practices, 4) action related to pharmaceutical exports to address global price discrimination, 5) the modification or revocation of drug approvals for unsafe, ineffective, or improperly marketed drugs, and 6) action to address what the EO refers to as global freeloading and price discrimination. The new EO is not specific to a type of drug or coverage (e.g., Part D), unlike the previously proposed MFN model which targeted Medicare Part B drugs.

On May 20, 2025, HHS announced the MFN price targets, based on a methodology similar to what was proposed under the MFN Model from the first Trump Administration. The MFN model faced legal challenges and was ultimately withdrawn by the Biden Administration and never implemented.<sup>29</sup> Under the updated formula, a drug's target price is the lowest price it is sold at in an OECD member country with a GDP per capita of at least 60% of the U.S. GDP per capita. More than 25 countries meet these criteria, including Germany, Norway, Japan, Korea, and Australia.

Following the publication of the EO and MFN price targets, the Administration met with pharmaceutical manufacturers to discuss how to achieve MFN pricing in the U.S. On July 31, 2025, the Administration announced that industry proposals have fallen short and sent letters to 17 biopharmaceutical CEOs calling for action on MFN pricing by September 29, 2025.<sup>30,3</sup> Specifically, the letters call for the manufacturers to extend MFN pricing to the Medicaid program, guarantee MFN pricing for newly launched drugs, return increased revenues abroad to American patients and taxpayers, and provide for direct purchasing at MFN pricing. It is unclear whether the Administration expects pricing actions or future commitments to pricing actions by September 29.

The EO and letters indicate the Administration expects progress toward the target prices to be achieved through voluntary equalized pricing in OECD countries and U.S. markets or a DTC offering, while threatening further action. The administration may pursue MFN pricing via rulemaking or legislation, or encouragement of FDA to exercise its authority to modify or revoke approvals for unsafe, ineffective, or improperly marketed drugs if manufacturers do not comply with MFN pricing.

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<sup>3</sup> Letters were sent to AbbVie, Amgen, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, EMD Serono, Genentech, Gilead, GSK, Johnson & Johnson, Merck, Novartis, Novo Nordisk, Pfizer, Regeneron, and Sanofi.

## Potential Impact of the MFN EO on Cancer Patients

**International Trade Action:** Ensuring fair pricing globally for oncology patients is important, but it should be approached thoughtfully and not pose short-term risks for U.S. patients. Tariffs and trade restrictions that disrupt the supply chains of critical oncology drugs and materials, including generic sterile injectables, chemotherapy agents, and other supportive care medications, could negatively impact patients.

Oncology medications and materials are crucial in cancer treatment protocols, and any shortages or increased out-of-pocket costs brought on by the U.S. or retaliatory countries could adversely affect patient care – driving up costs, compromising treatment effectiveness, and leading to worse patient outcomes. Balancing what other countries pay with the need for affordable and accessible cancer treatments in the U.S. will be crucial to ensure that patients do not bear the brunt of these trade policy shifts. Efforts to promote the affordability of cancer treatments is laudable; however, policies to address drug prices should also mitigate impacts on patient access.

**DTC Purchasing:** The adoption of DTC models for oncology medications is still in its early stages, as cancer treatment requires close coordination among oncologists, pharmacists, and nurses. Additionally, cancer patients often have co-morbid conditions, the treatment of which may interact with a chemotherapy treatment regimen.

Serious questions need to be addressed under the existing version of the policy to ensure patient safety and access. If implemented, DTC offerings should be fully integrated with care teams to avoid dosing errors, poor side-effect management, or treatment non-adherence. Additionally, DTC programs should be designed not to exacerbate inequalities for patients who are unfamiliar with the technology involved, financially unstable, or require complex oncology care.

**MFN Pricing Model:** Although the EO notes that an MFN model will be implemented by regulation only if ‘significant progress’ is not made toward the price targets, there were considerable access concerns associated with the initial MFN model that would need to be addressed in a new proposal. Under the previous framework, 50 Medicare Part B drugs would have been subject to a new payment methodology, the vast majority being hematology and oncology drugs.<sup>31</sup> While manufacturers were not required to lower prices, physicians would have been reimbursed at a lower rate. If providers had not been able to negotiate an acquisition price to keep them ‘above water,’ they likely would have declined to administer certain drugs, leaving cancer patients without access to those particular treatments. At the time, HHS acknowledged that there would be “significant uncertainty with these potential effects of the MFN Model,” as well as the potential for beneficiary access problems.<sup>32</sup> The Office of the Actuary estimated that the \$85.5 billion in estimated savings of the MFN model could largely be attributed to a lack of patient access to medication, rather than lowered drug prices for patients.<sup>xxxiii</sup>

Additionally, there has been interest in Congress in establishing an MFN model to address prescription drug prices. Notably, Sens. Bill Cassidy (R-LA) and Bernie Sanders (I-VT), chair and ranking member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, respectively, have each proposed their own versions of the MFN model. Sen. Cassidy’s latest reported proposal would require pharmaceutical manufacturers to increase prices for high-cost Medicare drugs in foreign markets or face claw backs of Medicare payments.<sup>33</sup> Sen. Sanders reintroduced the Prescription Drug Price Relief Act of 2025 (S. 1818) which, in contrast, would require HHS to conduct an annual assessment of drug prices and void exclusive rights for drugs that are deemed “excessively priced” based on international benchmarks.<sup>34</sup>

At a more general level, market-wide MFN implementation will be difficult to implement in the U.S. without significant legislative changes. While in other countries, market access may be denied based on price, the U.S.

does not have a mechanism to do so across markets (e.g., Medicare, Medicaid, commercial insurance). Without this ability, manufacturers face less pressure to lower their prices in the U.S. compared to other countries.

Affordable access to prescription therapies is essential for cancer patients. However, should MFN pricing be implemented by rulemaking or legislatively, policymakers will need to ensure that the framework does not deny cancer patients access to lifesaving prescription drug therapies.

**MFN Pricing:** IRA-related innovation concerns existed when government-negotiated prices were expected to apply to up to twenty high-spend Medicare drugs annually. If the expectation is for all drugs to meet MFN target prices broadly (i.e., regardless of payer), it is likely that substantially more profound concerns will arise from the sweeping scope.

A scan of manufacturer responses to MFN proposals highlights the infeasibility of implementing foreign pricing without addressing other aspects of the U.S. healthcare system.<sup>35</sup>

- **Takeda:** Takeda leadership highlighted how MFN is a challenging concept, noting that it does not account for structural differences in the U.S. healthcare system, like PBMs and the 340B program. Leadership further stated that the estimated impact of MFN in a Medicaid setting across the pharmaceutical industry would be \$1 trillion over 10 years, which would be a significantly challenging situation for the whole industry to handle.
- **Eli Lilly:** Eli Lilly leadership noted that MFN would need to be discussed in the context of net versus list prices in Europe, with the overall goal of changing how drugs are priced and innovation is funded across the continent.
- **Novartis:** Novartis leadership stated that MFN would have different levels of manageability based on the focus and details of the proposal, noting some scenarios would be devastating. Leadership further said that the U.S. should not import European price controls and a similar “anti-innovation” environment.
- **AbbVie:** AbbVie leadership noted that international reference pricing “leaves less investment available across the industry to advance new innovative medicines,” and the push should be for the EU to value innovation more properly.
- **Merck:** Merck leadership stated that PBM reform would be an important step to address the price differential between the U.S. and the rest of the world and noted that foreign governments should be encouraged to give fair value to innovation.
- **BMS:** BMS leadership agreed that countries outside of the U.S. need to allocate more healthcare spending to innovative medicines and similarly noted that \$0.65 of every \$1 spent on pharmaceutical products in the U.S. goes to “middlemen” who control what patients pay.

These initial comments suggest that absent other reforms, manufacturers’ approach to achieving MFN target prices may be more focused on raising prices in OECD countries versus lowering U.S. prices, which may not directly impact patient out-of-pocket costs in the U.S. However, should MFN prices be mandated, there could be a significant impact on companies’ abilities to continue innovation. As such, policymakers will need to mitigate potential impacts on the development of novel therapies to treat cancer.

## Conclusion

ACS CAN strongly supports efforts to make cancer treatments affordable and accessible for all patients. As the Administration and Congress consider reforms to the IRA, EOs to lower drug prices and establish MFN pricing, and related legislative proposals, they must consider the needs of cancer patients who rely on consistent access to

life-saving prescription drug therapies. No single oncology drug can treat all cancers – treatment must be tailored to fit the medical needs of each individual. As such, it is essential to balance efforts to improve affordability with the need to preserve patient choice and ensure continued investment in innovative cancer therapies.

While recent policy developments offer potential avenues to improve affordability, they also pose potential risks that must be carefully managed. Efforts to lower prescription drug prices must maintain the integrity, safety, and effectiveness of the U.S. drug supply, protect ongoing investment in oncology innovation, and ensure the continued development of future cancer treatments.

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