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# Price Isn't Value or Cost:
## Where ICER's Launch Price and Access Report Misses the Mark

## Introduction

In October 2025, the Institute for Clinical and Economic Review (ICER) released its Launch Price and Access Report to address growing concerns about rising drug prices in the United States (US), evaluating launch prices of 154 US Food and Drug Administration (FDA)-approved drugs (from 2022–2024) and patient access to these novel therapies.[1] ICER's analysis aimed to contribute to the drug pricing debate by assessing year-to-year trends in launch prices, evaluating the health system impact, and assess patient access barriers. ICER contends that, while pharmaceutical manufacturers have reported data demonstrating decreasing year-over-year net prices, the contribution of novel therapies towards overall pricing and access trends needs to be further examined.[1]

ICER's report concluded that drug launch prices are "rising unsustainably," with a 24% increase in the inflation-adjusted median annual launch price (list price) from 2022 to 2024, and a larger 51% increase in the median annual net launch price (i.e., the actual amount the manufacturer receives after rebates, discounts, and other reductions) after adjusting for inflation. After accounting for drug characteristics (e.g., orphan status, if the treatment is a cell or gene therapy), ICER estimated that annual launch price (list price) increased by 25% per year, while the annual net launch price increased by 33% per year. ICER also estimated that 16 of 23 drugs reviewed (70%) were priced above what it considers the fair "Health Benefit Price Benchmark" (HBPB), resulting in approximately $1.3-1.5 billion in "excess" first-year spending. The report claimed this excess spending translated to over 12,000 lost equal value life years (evLYs), nearly 100,000-115,000 individuals losing insurance coverage, and 351-415 preventable deaths.

ICER's report further evaluated patient access barriers for 2024 drug launches, finding that coverage policies frequently lag FDA-approval dates and that the majority of "new-to-brand" (i.e., first-time use of a brand versus continued therapies) prescriptions are rejected by payers. ICER argued that these findings demonstrate the need for value-based pricing aligned with its HBPB methodology and called for greater transparency in net drug pricing.

Nevertheless, ICER's simplistic approach had six significant flaws:

1. **ICER's analysis failed to follow Congressional Budget Office (CBO) best practices as it does not incorporate the ability of new pharmaceutical interventions to reduce medical costs.**
2. **ICER considered only initial annual price rather than costs over a patient's treatment horizon.**
3. **The report did not adequately consider how pharmaceutical prices impact the *total* cost to the US healthcare system, especially given evolving payer coverage restrictions.**

4. **ICER's reliance on quality-adjusted life years (QALYs) to establish the HBPB is both problematic for Medicare context and methodologically outdated.**
5. **ICER's HBPB is highly problematic due to a narrow perspective on value.**
6. **ICER ignores the fact that pharmaceutical spending is flat or falling as a share of total US healthcare spending.**

These critiques are discussed in the following six sections.

## Critique #1: ICER's analysis failed to follow Congressional Budget Office (CBO) best practices as it does not incorporate the ability of new pharmaceutical interventions to reduce medical costs.

When new prescription drugs are approved, the use of these pharmaceuticals often reduces spending on other medical services, such as hospitalizations, emergency department visits, and physician services, resulting in significant "cost offsets".[2-9] However, ICER consistently ignores evidence that new pharmaceuticals not only improve health outcomes but also reduce medical costs despite evidence of medical cost offsets shown across diseases and different populations.

Evidence of cost offsets attributable to pharmaceutical innovation has been documented across disease areas. In one study, patients with rheumatoid arthritis that initiated a biologic response modifier (BRM) experienced an approximate 20-27% reduction in physician visits within two years of initiation.[9] In another example, multiple sclerosis patients that underwent immunomodulatory therapy experienced a reduction in mean number of hospitalizations from 0.5 per patient per year to 0.3 per patient per year.[9] In another study quantifying the impact of pharmaceutical innovation on the average cost of U.S. healthcare episodes over 2000–2014, researchers found that drugs approved 5–20 years prior were associated with a 2–5% reduction in mean episode costs and a 10% reduction in hospital days.[4]

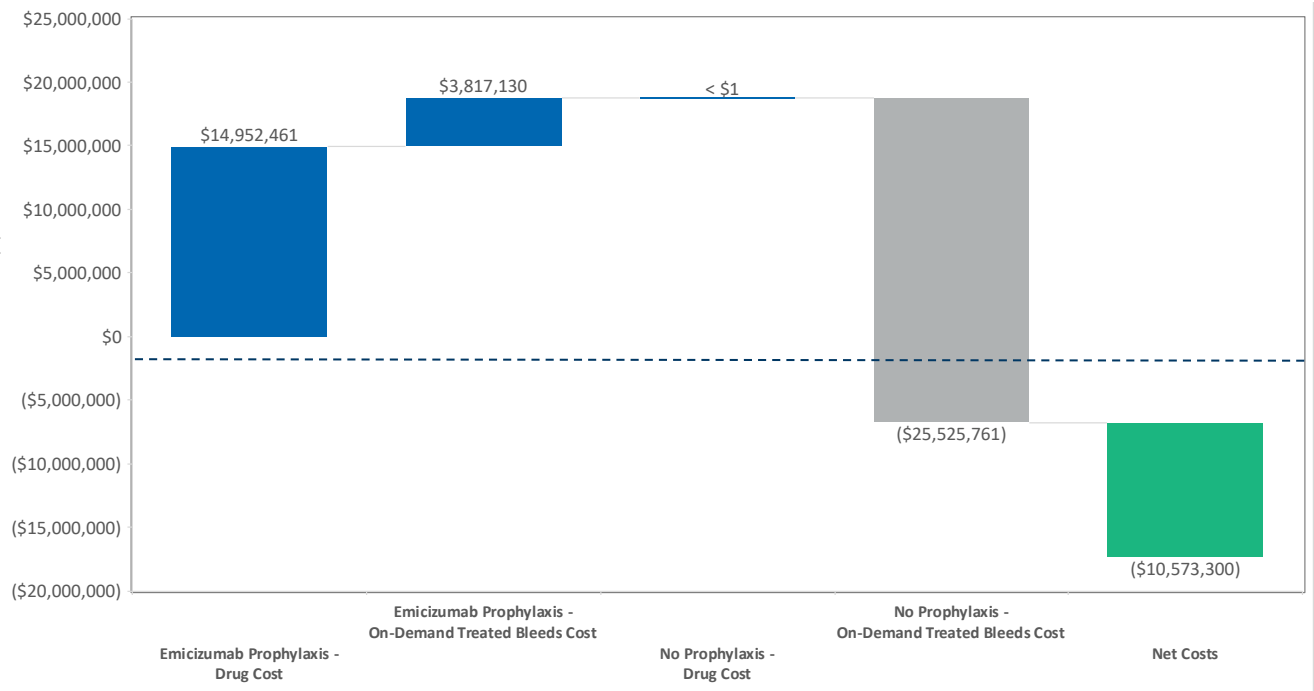
Cost offsets are common across patient populations by insurance coverage type. In the Medicare population, introduction of Medicare Part D prescription drug coverage reduced the overall rate of hospitalization by 20.5 per 10,000 (4.1%), representing approximately 42,000 admissions, about half of the reduction in admissions over 2005 to 2007 for 23 states. Furthermore, each additional prescription fill reduced hospital spending by $104 among Medicare beneficiaries.[10] Among Medicaid populations, a 1% increase in overall prescription drug use was associated with decreases in total non-drug Medicaid costs by 0.108% for blind or disabled adults, 0.167% for other adults, and 0.041% for children. A more recent analysis confirmed these findings, estimating that branded drug prices overstate the true long-run cost of pharmaceuticals by 40% to 75% when accounting for generic price reductions and medical cost offsets.[11]

The cost offsets from novel pharmaceutical drugs are consistently demonstrated not only in the US setting but also internationally. A study across 67 medical conditions in 15 OECD countries found that the estimated reduction in 2015 hospital expenditure attributable to post-1981 drug launches was 5.3 times as large as 2015 expenditure on those drugs.[8]

In fact, the federal government considers medical cost offsets when examining the impact of policies that change the number of new medications that come to market. The Congressional Budget Office (CBO), one of the federal government's most conservative and rigorous analytical agencies, estimates that a 10% increase in prescription drug use reduces Medicare spending on medical services by approximately 2%.[12] By focusing exclusively on drug acquisition costs without accounting for reductions in total cost of care, ICER's analysis does not adhere to government-recommended best practices and misrepresents the true economic impact of pharmaceutical innovation towards the US healthcare system.

To more fully understand the limitations of focusing solely on list price, consider the case of Hemlibra (emicizumab) prophylaxis for the treatment of patients with hemophilia A. ICER's own evidence report documented that emicizumab costs substantially more per year than their no prophylaxis assumption ($482,000 for the first year vs. $0 with no prophylaxis).[13] However, when accounting for the reduced costs associated with treating bleeding episodes, emicizumab was *cost saving*. For example, among patients ≥12 years old, lifetime cost of emicizumab accounting for on-demand treated bleed was $18.8 million ($15.0 million drug costs with $3.8 million in on-demand treated bleeds) compared to $25.5 million of no prophylaxis and on-demand treated bleeds (Figure 1). Similarly, COVID-19 vaccines increased pharmacy expenditures relative to no vaccination, yet numerous studies have demonstrated they generate substantial economic value. Research by Castillo et al. (2021) estimated that vaccines generated approximately $5,800 in benefit per course, yet the price of the vaccine was only $6–$40 per course. Despite a large budget impact due to COVID spending, the development of the COVID vaccine saved billions of dollars in medical costs through prevented hospitalizations, ICU admissions, and deaths, not to mention the broader benefits to the global economy.[14] These cases illustrate how ICER's focus on annual drug prices, without a complete consideration of medical cost offsets, can lead to fundamentally misleading conclusions about pharmaceutical value and potentially limit patient access to therapies that would ultimately reduce total healthcare spending.

***Figure 1. Health System Perspective Results from ICER: Emicizumab Prophylaxis Compared to No Prophylaxis***




Source: ICER, "Emicizumab for Hemophilia A with Inhibitors: Effectiveness and Value. Final Evidence Report", 2018 [13]

## Critique #2: ICER considered only initial annual prices rather than costs over a patient's treatment horizon.

ICER's approach of focusing on initial annual prices rather than lifetime treatment costs is also problematic, particularly for curative or one-time therapies such as gene therapies, where a single upfront payment may replace decades of chronic disease management. For instance, ICER's Launch Price and Access Report only considered the one-time net price of $2.2 million for Casgevy and $3.1 million for Lyfgenia gene therapies for sickle cell disease (SCD) and ignores the fact that costs under standard care amounts to $1.5 million over a patient's lifetime, as estimated in ICER's Evidence Report "Gene Therapies for Sickle Cell Disease."[15] While gene therapies such as etranacogene dezaparvovec (EDZ) for hemophilia B cost approximately $3.5 million (list price; ICER estimated $2.6 million net price), they eliminate the need for Factor IX prophylaxis treatments that accumulate to $14.5 million over a patient's lifetime, resulting in approximately $11 million in savings.[1,16]

Moreover, ICER's methodology also failed to account for how the Inflation Reduction Act (IRA) has fundamentally altered pharmaceutical pricing trajectories. The IRA mandates inflation caps that effectively limit annual drug price increases to the rate of inflation, resulting in a 0% annual

inflation-adjusted rate of price increase in real terms. This means that drug manufacturers may set higher list prices at launch while actually decreasing total cost to the health care system over time. To understand why this is the case, consider a stylized example where pre-IRA a drug's launch price was $10,000 per year and that price increased by a fixed $500 each year. In comparison, consider the same drug in the post-IRA world that sets a launch price that is 25% higher (i.e., $12,500) but experiences no inflation-adjusted price growth due to the inflation cap (Table 1). After 12 years, the pre-IRA price increases result in a drug price of $16,000, whereas the post-IRA price remains constant (in real terms) at $12,500. Assuming either constant patient uptake of 10% annually or variable uptake that increases by one percentage point per year, the 12-year average annual drug costs are *lower* in the case where launch price is higher due to IRA restrictions.

***Table 1. Hypothetical Example of Pre-IRA and Post-IRA Launch Price Impact on Annual Drug Prices Over Time***

| Scenario | Initial Launch Price | Price After 12 Years | Average Annual Drug Cost (Constant Uptake: 10% Each Year) | Average Annual Drug Cost (Variable Uptake: 1% Increase Per Year) |
|---|---|---|---|---|
| **Post IRA** | $12,500 | $12,500 | $16,250 | $11,375 |
| **Pre-IRA** | $10,000 | $16,000 | $16,900 | $12,740 |
| **Difference ($)** | $2,500 | -$3,500 | -$650 | -$1,365 |
| **Difference (%)** | 25.0% | -21.9% | -3.8% | -10.7% |

See Table A1 for details.

In addition to current IRA inflation caps, the government has started negotiating Maximum Fair Prices with manufacturers for select Medicare Part D drugs (effective 2026) and Part B drugs (effective 2028), further limiting pharmaceutical drug price increases.[17] As a result, annual drug price increases will be lower over time under IRA policy regulations, not necessarily "rising unsustainably" as ICER suggests.

ICER's approach also neglects the impact of market competition on pharmaceutical prices over time. New competitors and patent expirations typically lead to significant decreases in net prices, even when list prices remain stable.[18] For example, the market for treating the hepatitis C virus (HCV) illustrates this dynamic. When Gilead's Sovaldi (sofosbuvir) was first launched, it quickly became the dominant therapy, accounting for 78.2% of all US HCV antiviral expenditures in 2014.[19] FDA-approval of other branded direct-acting antivirals, particularly Merck's Zepatier (elbasvir/grazoprevir) in 2016 and AbbVie's Mavyret (glecaprevir/pibrentasvir) in 2017 created significant competition and pricing pressure on Gilead's Sovaldi (and Harvoni [ledipasvir and sofosbuvir], regimen for HCV genotype 1 infection specifically). Mavyret, for instance, had a lower launch price of $26,400 per treatment course compared to $84,000 for Sovaldi and $94,500 for

Harvoni, providing payers and providers with a lower cost alternative.[20-22] This new branded competition reshaped the market by influencing both pricing and treatment uptake, resulting in negotiated discounts on Sovaldi and Harvoni reportedly up to 46% off list price in 2015, with Mavyret capturing 41.0% of market share in 2019, illustrating how non-generic entrants can quickly alter dynamics even in a market previously dominated by a single brand.[22,23]

Similarly, the economic impacts of market competition on drug pricing can also be observed in the GLP-1 market, which focuses on type 2 diabetes and obesity interventions. In November 2025, Novo Nordisk reduced drug prices for Ozempic from $1,000 per month to $350 per month, and Wegovy from $1,350 per month to $349 per month.[24] These reductions directly responded to major competitor Eli Lilly's decision to cut the drug price for Zepbound from $1,086 per month to $346 per month, which strategically aimed to enhance patient access to GLP-1 therapies.[24]

By concentrating on launch prices and failing to model competitive dynamics over a patient's treatment horizon, ICER's methodology does not reflect the real-world pricing environment where multiple entrants drive substantial price concessions through increased rebating and contracting.

## Critique #3: The report did not adequately consider how pharmaceutical prices impact the total cost to the US healthcare system, especially given evolving payer coverage restrictions.

As more payers use utilization management (UM) initiatives, such as step therapy and prior authorization (PA) requirements, patients are increasingly facing barriers that prevent them from accessing therapies even when priced within ICER's HBPB. This means that the quantity of new drugs used may be falling.

Payer use of utilization management strategies has become more frequent in recent years. A University of Southern California study showed that restricted—coverage under PA or step therapy—non-protected-class drugs in Medicare Part D plans increased from 31.9% in 2011 to 44.4% in 2020. The restrictions were particularly high among brand-name compounds with plans excluding 44.7% from coverage and placing 23.7% under PA or step therapy, leading to 68.4% of brand-name-only compounds with utilization restrictions in 2020.[25] Panzer et al. (2022)'s examination of commercial plan coverage for drugs approved in 2018 found widespread utilization management: across 4,697 formulary entries, 82% included UM with 98% of restricted entries requiring PA and 70% placed on the highest cost-sharing tier.[26] Even high-priority treatments such as orphan drugs and oncology treatments faced significant restrictions (68% and 64% placed on the highest tier, respectively).[26]

ICER's own 2025 Launch Price and Access Report confirmed that payers are increasingly using utilization management techniques to reduce access.[1] The majority (58%) of commercial new-to-

brand prescriptions (i.e., a patient's first-time prescription of a drug, not a refill) for newly approved drugs in 2024 were rejected due to non-coverage, PA or step therapy, with an average of only 29% of total new-to-brand prescriptions ultimately being successfully filled. More specifically, 23% of new-to-brand prescriptions were rejected due to PA or step therapy on average. The report also found that "rejection rates [proportion of new-to-brand prescriptions that were rejected due to non-coverage or UM in the first quarter of 2025] were greater than 50% regardless of whether the drug was first-in-class, considered an orphan drug, or deemed cost-effective by ICER". Furthermore, one in four prescriptions of first-in-class, orphan, or priced-to-value ("as determined by a drug's net price in relation to the ICER Health Benefit Price Benchmark") drugs were rejected specifically due to PA or step therapy.

Rejection rates exceeded 50% regardless of whether the drug was first-in-class, considered an orphan drug, or deemed cost-effective by ICER. For non-oncology drugs, rejection rates were even higher at 63%, compared to 42% for oncology medications. ICER's analysis of specific medications revealed alarming access barriers – for example, despite 72% of commercial payers appearing to cover Rezdiffra for MASH, 76% of commercial new-to-brand prescriptions were rejected (46% due to UM) and only 6% were ultimately filled. Even drugs "priced to value" according to ICER's own benchmarks faced significant access restrictions, with 65% of prescriptions rejected of which 30% were due to UM, demonstrating that pricing aligned with ICER's value assessments does not necessarily translate to better patient access.

As any economist knows, total cost is a function of both price and quantity. As payers increasingly use UM to restrict access to medications—constraining the number of pharmaceuticals that patients can access—it is not clear that higher prices are resulting in more cost to the health care system. For example, a drug that costs $10,000 per year to treat 10,000 patients would lead to $100 million in total pharmaceutical spending. However, if launch prices increased 25% (based on ICER's report) to $12,500, but UM reduced access to only 47% of patients (as ICER found for Ohtuvayre [ensifentrine]), then actual spending would be lower at $58.8 million in total pharmaceutical spending.[1] In other words, despite 25% higher list prices, pharmaceutical companies actually receive 41.2% less revenue.

Additionally, the impact of UM on cost to the health care system is not captured in the ICER report. A systematic review by Park et al. (2017) found that while formulary restrictions (PA and step therapy) reduced drug utilization and pharmacy costs, these savings were frequently offset by higher medical costs and worse patient outcomes.[27] For instance, restricting access to novel anticoagulants was shown to reduce use of the targeted drugs but also increased the risk of stroke among patients newly diagnosed with atrial fibrillation.[28] The 2024 American Medical Association (AMA) physician survey underscores clinicians' concerns on increasing UM, with 82% of physicians reported that prior authorization frequently leads to treatment abandonment, 29%

noting associations with serious adverse events, and 23% indicating PA resulted in a patient's hospitalization.[29]

Together, these findings demonstrate that payers' restrictive coverage policies often undermine access to clinically valuable therapies and may worsen downstream outcomes. This highlights a persistent gap between value-based pricing frameworks and real-world patient access, and thus leads to potentially incorrect estimation of total healthcare spending on new pharmaceuticals. In short, ICER's focus on list and net prices without comprehensive assessment of how increased use of UM impacts total cost to the health care system results in an incomplete picture of affordability.

## Critique #4: ICER's reliance on quality-adjusted life years (QALYs) to establish the HBPB is both problematic for Medicare context and methodologically outdated.

According to ICER's Launch Price and Access Report, the total excess spending on the 16 drugs with prices above their calculated HBPB was estimated to be between $1.3 billion and $1.5 billion in 2023.[1] ICER arrives at this conclusion by comparing actual net prices of new drugs to what they consider "fair prices" based on their HBPB, which is derived from cost-effectiveness analyses assuming a threshold of $100,000 per QALY and an equal value life years (evLY) threshold of $150,000 per QALY.

However, ICER's approach relies on an outdated and controversial methodology to arrive at these conclusions on pharmaceutical spending. The Affordable Care Act of 2010 explicitly prohibits the use of any metric that "treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill" (i.e., QALYs).[30,31] This was further reinforced by the IRA for the Medicare Drug Price Negotiation Program. However, ICER's benchmarks are fundamentally QALY-based and its reliance on conventional QALYs is therefore problematic in public payer contexts, and alternative approaches should be utilized to focus on value-based price calculation.

While QALY-alternative methods such as Health Years in Total (HYT) and evLY (which ICER uses) attempt to address equity concerns, there are limitations to both. The HYT approach incorporates both longevity and quality of life while avoiding the multiplicative assumption of QALYs, but it still relies on predetermined utility weights that may not reflect individual patient values or adequately account for disease severity.[32] The evLY measures health gains solely in terms of life-years and quality of life gains during the life span under the old standard of care.[33] However, evLYs can overvalue treatments that extend life with poor quality of life and fail to capture the full burden of living with severe illness, potentially disadvantaging patients whose treatments primarily improve quality of life during the life extension phase.

The Generalized Risk-Adjusted Cost-Effectiveness (GRACE) model addresses shortcomings of HYT and evLY by introducing diminishing returns to health-related quality of life, fundamentally changing how health improvements are valued. GRACE demonstrates that willingness to pay for health improvements should increase exponentially with illness severity meaning cost-effectiveness thresholds should be substantially higher for severe diseases and lower for mild conditions.[34] This approach recognizes that health is worth more to those who have less of it, directly addressing the discrimination concerns of QALYs and evLYs. GRACE also accounts for patients' risk aversion and the value of reducing uncertainty in treatment outcomes, providing a more comprehensive framework that better aligns with patient-centered values and societal preferences for prioritizing treatments for severe conditions.

Perhaps more importantly, ICER's use of an arbitrary "shared savings" approach to calculate HBPB does not fully account for cost offsets from reduced usage of the comparator therapy. Ignoring cost offsets from switching from a comparator therapy is an approach that does not follow economic best practices. To see why this matters, consider ICER's March 2024 review of iptacopan for paroxysmal nocturnal hemoglobinuria (PNH). ICER's traditional threshold analysis (before considering the shared savings scenario) determined that a price of $507,000 per year for iptacopan would meet the cost-effectiveness thresholds of $100,000 per QALY. This means that ICER's own analysis recommended a modest discount of approximately 7.8% compared to iptacopan's annual wholesale acquisition cost of $550,377. However, ICER applied its shared savings assumptions (where $150,000 annual cap on cost offsets was applied) and reported a HBPB of $178,000, at $100,000/QALY threshold, and suggested a significantly larger discount of 67.6%.[35] ICER's HBHP based on its shared savings algorithm is out of line with their primary analysis/base case findings. Furthermore, ICER's shared savings scenario analysis for iptacopan disregarded the full cost offset of ravulizumab and other C5 inhibitor therapies, creating the de facto assumption that comparator treatment is incrementally valued at an arbitrary $150,000, resulting in a misrepresentation of HBPB. One study found that ICER's shared savings approach would most likely have the largest negative impact on calculating HBPB for rare, severe, and pediatric diseases, potentially undervaluing pharmaceutical innovation in these areas of high unmet need.[36]

## Critique #5: ICER's Health Benefit Price Benchmark is highly problematic due to a narrow perspective on value.

ICER's approach to calculating HBPB warrants significant concern over its ability to accurately calculate value-based prices for drugs, as it fails to account for broader societal benefits as recommended by leading health economists in the GCEA as mentioned above. The GCEA framework identifies 15 value elements across four categories—uncertainty, dynamics, beneficiary, and additional value components—that should be incorporated when assessing

societal value.[37] These include productivity gains, caregiver spillover effects, equity considerations, option value, scientific spillover, and community spillovers. However, ICER's analysis does not consider a societal perspective and other value elements (e.g., insurance value for rare disease interventions). By ignoring these broader value elements, ICER substantially underestimates the societal return on investment from pharmaceutical innovation.

To understand why this narrow perspective is problematic, consider ICER's evaluation of sickle cell disease (SCD), which found an HBPB range of $1,350,000 to $2,050,000 for both Casgevy (launch price $2,200,000) and Lyfgenia (launch price $3,100,000), which ICER concluded to provide insufficient value.[1] However, ICER failed to capture the important value of these treatments have on society in terms of reducing health inequities, considering more than 90% of SCD patients are Black Americans, whose average life expectancy at birth of 74.0 years was lower compared to 78.4 years of White individuals.[38,39] Yet, ICER's evaluation using traditional cost-effectiveness analysis failed to capture this important element of value. More broadly beyond SCD, researchers who applied GCEA methods to treatments previously evaluated by ICER found that while only 8 of the 20 medicines produced value for money to society under traditional QALY-based cost-effectiveness analysis, at least 17 of the 20 medicines produce value after accounting for disease severity and dynamic pricing.[40] This suggests that ICER's HBPB analysis for new treatments failed to account for significant value of medical innovation to society that are critical to evaluating these transformative therapies.

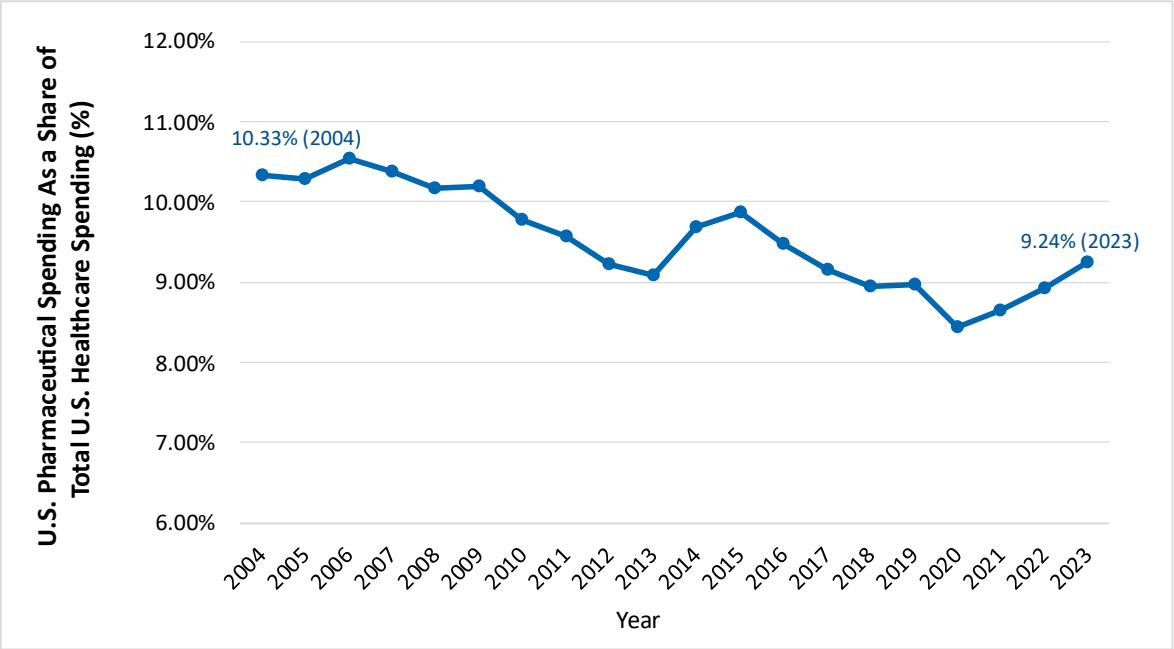
In summary, because of a lack of focus on broader value and ICER's ad hoc assumptions unsupported by the literature, ICER's conclusion of "overspending on pharmaceuticals" is based on a narrow view of these medications' impact on broader society. A more comprehensive evaluation framework that incorporates the full spectrum of value elements would likely yield different conclusions about value-based drug pricing. Until ICER adopts a more holistic methodology that aligns with established health economic standards, its HBPB assessments will continue to raise concern about whether they accurately assess the true economic impact of pharmaceutical innovation to the healthcare system.

## Critique #6: ICER ignores the fact that pharmaceutical spending is flat or falling as a share of total US healthcare spending.

ICER's Launch Price and Access Report's narrative suggests that pharmaceutical spending is overtaking all other forms of healthcare spending in the US and is a leading cost concern. However, a closer examination of healthcare expenditures demonstrates that pharmaceutical spending as a share of total US health expenditures has been flat, or even decreased, over time (Figure 2). According to the Centers for Medicare and Medicaid Services (CMS) National Health Expenditure Accounts (NHEA), prescription drug spending accounted for 9.2%of total national health expenditure in 2023, a decrease from 10.3% in 2004.[41,42] Although high-cost specialty and

oncology drugs have contributed to increases in absolute pharmaceutical expenditures, the overall share of healthcare spending on prescription drugs has remained the same or decreased over time.[43] These figures demonstrate that, although launch prices for pharmaceuticals has increased, their proportion of total healthcare spending has remained relatively stable over the past two decades.

***Figure 2. Trend in U.S. Pharmaceutical Expenditure as a share of total US healthcare spending (2004-2023)***




Source: Centers for Medicare and Medicaid Services (CMS), National Health Expenditure Data, 2025.[44]

Furthermore, the latest National Health Expenditure Projections show that the overall prescription drug spending growth is projected to slow from 7.0% in 2025, to 5.6% for 2026-2027, and 4.7% for 2028-2033.[45] These data indicate that increases in pharmaceutical spending have generally occurred in line with overall growth in healthcare expenditures, but are projected to decelerate over the next eight years due to various policy implementations, such as IRA price negotiations, rather than representing a markedly larger share of total healthcare spending.

In summary, empirical evidence indicates that while pharmaceutical expenditures have increased in absolute terms, their relative share of total healthcare spending has remained largely stable or has declined slightly over the past two decades. This evidence suggests that ICER's representation of drug spending as "unaffordable" does not accurately reflect trends observed in national data.

## Conclusion

This analysis has identified six fundamental flaws in ICER's Drug Launch Price and Access Report that significantly undermine its conclusions about pharmaceutical pricing and value. First, ICER's methodology fails to incorporate critical cost offsets that often make innovative therapies cost-saving over time, despite their higher initial prices. Second, by focusing narrowly on annual prices rather than lifetime treatment costs, ICER misrepresents the economic value of curative and one-time therapies that eliminate years of chronic disease management expenses. Third, the report also overlooks how increasing payer coverage restrictions and utilization management practices mean that pharmaceutical companies are likely receiving less money for each drug launched even as list prices are increasing. Fourth, ICER's continued reliance on QALY-based methodologies is particularly problematic given legal prohibitions in Medicare contexts and the availability of more equitable alternatives such as the GRACE model that better account for disease severity and patient preferences. Fifth, ICER's HBPB employs a narrow perspective that excludes broader societal benefits recognized by leading health economists, including productivity gains, caregiver effects, and equity considerations. This approach systematically undervalues pharmaceutical innovation, particularly for treatments addressing rare diseases and conditions affecting populations with existing health inequities. Finally, contrary to ICER's narrative of unsustainable pharmaceutical spending growth, national health expenditure data demonstrates that prescription drug spending has remained stable or decreased as a proportion of total healthcare costs over the past two decades, with projections showing further decreases due to IRA implementation.

Taken together, these methodological shortcomings render ICER's conclusions about "excess" pharmaceutical spending and pricing unsupported by comprehensive economic analysis. A more holistic evaluation framework that incorporates full cost offsets, lifetime treatment horizons, access realities, equitable value assessment, and accurate spending trends would likely yield substantially different conclusions about the value and affordability of pharmaceutical innovation in the US healthcare system.

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# Appendix

### *Table A1. Year-by-Year Table Comparing Pre-IRA Price vs. Post-IRA Price*

| Scenario | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 | 2035 | 2036 | 2037 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Uptake | 1.0% | 2.0% | 3.0% | 4.0% | 5.0% | 6.0% | 7.0% | 8.0% | 9.0% | 10.0% | 11.0% | 12.0% | 13.0% |
| Post IRA Price | $ 12,500 | $ 12,500 | $ 12,500 | $ 12,500 | $ 12,500 | $ 12,500 | $ 12,500 | $ 12,500 | $ 12,500 | $ 12,500 | $ 12,500 | $ 12,500 | $ 12,500 |
| Pre-IRA Price | $ 10,000 | $ 10,500 | $ 11,000 | $ 11,500 | $ 12,000 | $ 12,500 | $ 13,000 | $ 13,500 | $ 14,000 | $ 14,500 | $ 15,000 | $ 15,500 | $ 16,000 |
| Difference | $ 2,500 | $ 2,000 | $ 1,500 | $ 1,000 | $ 500 | $ - | $ (500) | $ (1,000) | $ (1,500) | $ (2,000) | $ (2,500) | $ (3,000) | $ (3,500) |
| Difference % | 25.00% | 19.05% | 13.64% | 8.70% | 4.17% | 0.00% | -3.85% | -7.41% | -10.71% | -13.79% | -16.67% | -19.35% | -21.88% |

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FTI Consulting's Center for Healthcare Economics and Policy applies cutting-edge economics and quantitative methods to assist clients in developing and implementing market-based solutions across a wide spectrum of healthcare activity. We use economic and financial modeling in developing evidence-based strategies to address fundamental changes in healthcare demand and delivery within a healthcare system or a region. Our advanced capabilities and extensive data sets can address effects of major policy, regulatory, or significant and disruptive changes on healthcare systems or communities, whether local, regional, national or international. We provide predictive modeling capable of evaluating complex "what-if" scenarios for both public and private stakeholders.

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