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The Drug Pricing Reset

Navigating the IRA's Impact on Access, Innovation, and Rare Disease Economics

A Strategic Guide for Market Access and Commercial Leaders

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The Drug Pricing Reset reflects an effort by Alkemi to highlight emerging trends in market access. The information presented is a synthesis of the views of Alkemi and is intended for research purposes only.

Executive Summary

The New Era of Drug Development:

For the first time in modern U.S. history, federal policy is directly reshaping how branded drugs are priced and accessed. The Inflation Reduction Act (IRA) marks a structural shift away from industry-led pricing toward a policy-driven access framework, with Medicare now negotiating prices for select high-expenditure drugs beginning in 2026.

Exhibit 1: Strategic Imperatives for Commercial and Market Access Leaders

Beyond negotiation, the IRA redesigns Medicare Part D by capping patient out-of-pocket spending, penalizing price increases above inflation, and shifting greater financial risk to manufacturers and insurers[1]. These changes materially alter incentives across the product lifecycle, compressing timelines and raising the bar for evidence, pricing defensibility, and negotiation readiness.

The reforms are intentionally targeted. Price negotiation focuses on widely used, high-cost drugs for common conditions, while rare disease therapies remain protected through orphan drug exemptions and subsequent legislative refinements. This bifurcation reshapes portfolio strategy and access planning, particularly for companies balancing common-disease scale with rare-disease innovation.

For market access, HEOR, and commercial strategy leaders, pricing power can no longer be assumed. Value must be demonstrated earlier, defended continuously, and aligned with evolving policy and payer expectations. Organizations that integrate evidence strategy, policy fluency, and access planning into core decision-making will be best positioned to secure sustainable access in this new environment.

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Traditional US Drug Pricing and Access

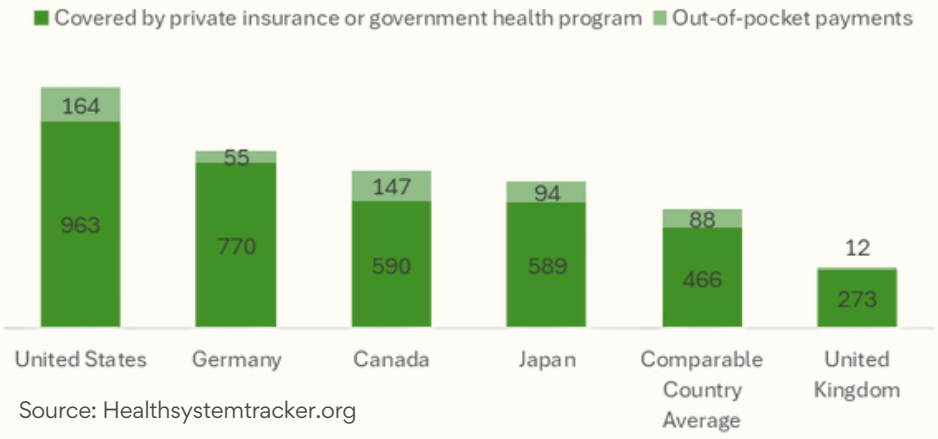
The U.S.'s historical free-pricing system fueled global pharmaceutical innovation, but Americans paid the highest drug prices in the world and often had to rely on complex workarounds to access expensive therapies.

For decades, U.S. drug pricing operated under a market-driven model in which manufacturers set launch prices with limited direct government intervention. This approach positioned the United States as the primary revenue engine for global pharmaceutical innovation, with prices substantially higher than those in other developed markets[2]. Insurers and pharmacy benefit managers (PBMs) served as the primary negotiating intermediaries, using confidential rebates and formulary placement to manage access and cost. Medicare, however, was legally barred from direct price negotiation under the 2003 noninterference clause, leaving pricing outcomes largely shaped by commercial contracting rather than public purchasing power[3].

Market access under this system depended on complex tradeoffs. Manufacturers exchanged rebates for coverage and formulary position, while payers used tiering, utilization management, and patient cost-sharing to control spending. High-cost therapies were frequently placed on specialty tiers, limiting affordability even when nominally covered.

For rare disease therapies, manufacturers relied on orphan exclusivity, patient assistance programs, and selective outcomes-based agreements to secure access for small patient populations. Despite these mechanisms, patients often faced coverage delays, denials, or significant out-of-pocket exposure due to high list prices. This pricing framework delivered strong innovation incentives, but left patients and public payers exposed to high and rising costs, contributing to growing affordability concerns and pressure for policy intervention.

Exhibit 2: Average Country Drug Spend



Source: Healthsystemtracker.org

The U.S. leads all peer nations in per capita spending on prescription medicines, driven overwhelmingly by higher insurer and government program payments. Highlighting the outsized financial burden and underscoring the urgency behind recent U.S. drug pricing reforms

A Historic Shift in Drug Pricing

The Inflation Reduction Act of 2022 introduced a targeted intervention into U.S. drug pricing policy.

THE INFLATION REDUCTION ACT: A WATERSHED EVENT

The Inflation Reduction Act of 2022 marked a decisive change in U.S. drug pricing policy. For the first time, Medicare was authorized to directly negotiate the prices of select high-expenditure, single-source drugs that lack generic or biosimilar competition[1].

Under the IRA, Medicare moves from a passive payer to an active negotiator for both Part D and, over time, Part B drugs. While the scope of negotiation is limited, the precedent is significant: federal price negotiation is now embedded in U.S. healthcare policy, regardless of future administrations.

Each year, a defined number of drugs are selected for negotiation based on total Medicare spending and market exclusivity. In 2023, the Centers for Medicare & Medicaid Services (CMS) identified the first ten Part D drugs for negotiation, including therapies for diabetes (Januvia, Farxiga, Jardiance), heart failure (Entresto), blood clots (Eliquis), and autoimmune disease (Enbrel). Collectively, these products accounted for approximately $50.5 billion—roughly 20% of total Part D drug spending—highlighting the program's focus on medications that are both high-cost and widely used[1].

HOW IRA NEGOTIATION WORKS

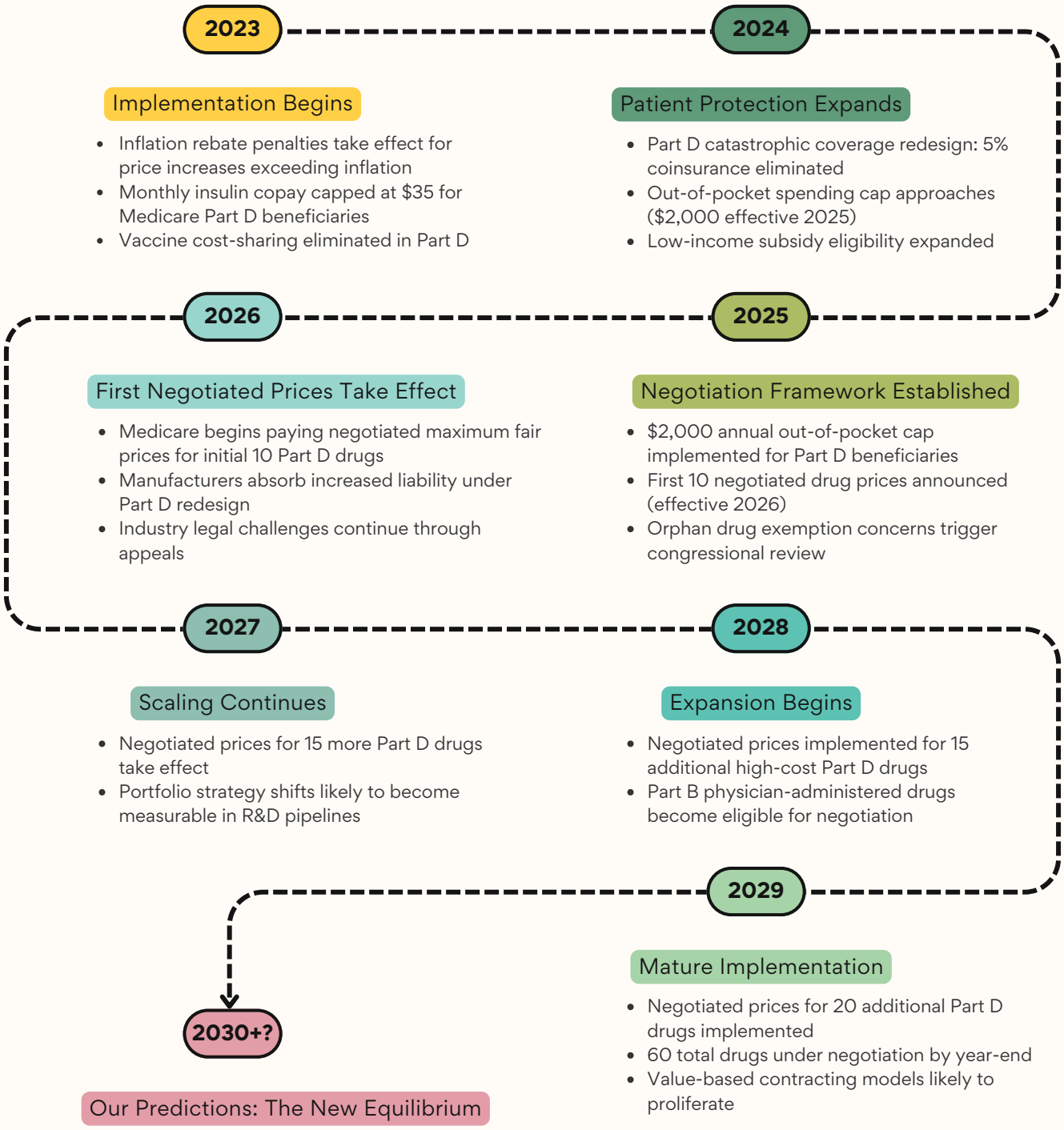
CMS negotiates a "maximum fair price" (MFP) for each selected drug through a structured, multi-month process. Manufacturers must enter into an agreement and submit detailed data on clinical benefit, unmet need, R&D costs, production, and sales. Unlike private-market negotiations, participation is mandatory; refusal to engage triggers excise taxes of up to 95% of a drug's U.S. sales, effectively compelling compliance[4].

CMS evaluates submitted evidence and issues an initial price offer, followed by negotiations that conclude with a final MFP published by September of the year preceding implementation[5]. The first negotiated prices will take effect in 2026.

Once a price is set, all Medicare Part D plans must cover the drug at the negotiated MFP. This guarantees coverage, reduces patient cost-sharing, and eliminates the need for manufacturers to secure formulary placement through large rebates.

To partially offset revenue impact, drugs with negotiated prices are exempt from certain Medicare rebates and discounts, including portions of the Part D coverage-gap liability. Depending on the size of the negotiated price reduction and prior rebate exposure, a product's net revenue under negotiation may be comparable to its pre-IRA net position after rebates and discounts.

Exhibit 3: Inflation Reduction Act Timeline



Scenario-based projections

- Congressional amendments fine-tune small-molecule vs. biologic timelines based on innovation data
- International reference pricing proposals resurface as budgetary pressures mount
- Biosimilar and generic competition moderates prices for aging negotiated drugs
- Payer-manufacturer outcomes-based agreements become standard for specialty therapies
- Market access functions fully integrated into early-stage portfolio decisions
- Rare disease exemptions face scrutiny; potential means-testing or price caps debated

The Inflation Reduction Act introduces drug pricing reforms in stages, beginning with inflation penalties and insulin copay caps in 2023. Medicare drug price negotiations begin in 2026, scaling up through 2029 to include 60 high-cost Part D drugs. These phased reforms are reshaping market dynamics and payer risk across the drug lifecycle.

BROADER AFFORDABILITY REFORMS

Beyond negotiation, the IRA introduced a series of affordability reforms that materially reshape Medicare Part D. Beginning in 2025, beneficiary out-of-pocket spending is capped at $2,000 annually, eliminating unlimited exposure for patients on high-cost therapies. The law also penalizes manufacturers for price increases that exceed inflation through mandatory inflation rebates.

In addition, the IRA capped Medicare patients' monthly insulin copays at $35, signaling a willingness to target specific high-profile drug categories. Collectively, these provisions shift a greater share of financial risk away from patients and onto manufacturers and plans, fundamentally redesigning Part D's cost-sharing structure.

WHY THE IRA WAS A MAJOR SHIFT

Politically and economically, Medicare price negotiation represents a fundamental change in how drug spending is managed in the United States. Medicare's historical inability to negotiate prices was frequently cited as a key driver of higher U.S. drug costs relative to peer countries. With the IRA, Congress explicitly sought to rein in spending; the Congressional Budget Office projected more than $90 billion in savings from the negotiation provision alone over its first decade[1].

In practice, the U.S. government now wields leverage more comparable to European health systems, though in a narrower, more targeted form. Only a limited number of older, high-spend drugs are eligible for negotiation each year, but the shift in negotiating authority alters expectations across the drug lifecycle.

Manufacturers increasingly view these changes as constraints on the long-standing U.S. pricing model. Industry leaders argue that price negotiation may reduce incentives for innovation, particularly for mid-lifecycle products. The IRA's asymmetric timelines, small-molecule drugs becoming negotiation-eligible after nine years versus thirteen years for biologics, have intensified these concerns and raised questions about R&D investment distortions[6].

Early analyses suggest companies may respond by prioritizing biologics or scaling back small-molecule development, with one report noting a significant decline in small-molecule R&D funding following the proposal of IRA pricing provisions[7]. These concerns have prompted bipartisan discussions around potential policy refinements, including proposals to align small-molecule and biologic timelines.

Regardless of future adjustments, the IRA establishes a durable precedent: federal involvement in drug price setting is now a structural feature of the U.S. healthcare system. Even if modified at the margins, Medicare price negotiation is likely to remain a permanent constraint shaping pharmaceutical pricing, access, and evidence strategy.

The White House Push and Industry Response

ESCALATING FEDERAL PRESSURE AND INDUSTRY RESISTANCE

In recent years, the White House has taken an increasingly aggressive stance on drug pricing across both Democratic and Republican administrations. President Biden's administration celebrated the IRA's first batch of negotiation-eligible drugs as a victory for patients and warned pharmaceutical companies against obstruction. By 2025, President Trump escalated dramatically: an executive order demanded "most-favored-nation" pricing, requiring U.S. prices to match the lowest charged abroad, and letters to 17 major pharmaceutical CEOs imposed a September 29 deadline for pricing commitments[8][9]. The President warned that refusal would trigger "every tool in our arsenal," including potential regulatory actions, facilitated drug importation, or even 100% tariffs on certain pharmaceutical imports[10][11].

This unprecedented ultimatum made clear the administration expected compliance or consequences. Few companies volunteered the broad U.S. price cuts required, underscoring the revenue impact and global pricing disruption such commitments would entail. Analysts widely predicted this outcome, noting that voluntarily slashing U.S. prices to match the lowest international levels would result in massive revenue losses[12]. Many viewed the hardline stance as negotiating theater rather than practicable policy. By late 2025, the approach had softened slightly, threatened tariffs were paused amid supply disruption concerns, but the signal to industry remained unmistakable.

LEGAL BATTLES AND PRAGMATIC COMPLIANCE

Industry response has been adversarial but ultimately pragmatic. Pharmaceutical companies and their lobbying groups, led by PhRMA, have forcefully opposed Medicare price negotiation in both rhetoric and court. Numerous lawsuits have been filed since 2023 challenging the IRA on constitutional grounds. Merck, Bristol Myers Squibb, Johnson & Johnson, Novartis, and others argued the program constituted unconstitutional taking or compelled speech violations.

Judicial reception has been unsympathetic. Multiple federal courts rejected industry claims that negotiations were coercive or exceeded congressional authority, though appeals continue. These legal challenges have functioned primarily as delaying tactics and symbolic objections rather than effective barriers to implementation.

Despite vocal opposition, companies have complied. All ten manufacturers whose drugs were selected for first-round Medicare negotiations signed participation agreements by the deadline with some explicitly noting they did so "reluctantly." For the first time, major pharmaceutical firms are negotiating prices directly with the U.S. government, something unthinkable before the IRA. Companies have conceded pricing power in the Medicare market while maintaining their participation is under protest and duress.

STRATEGIC CONCESSIONS ON HIGH-PROFILE PRODUCTS

Beyond legal resistance, the confrontation triggered behind-the-scenes negotiations and limited, strategic concessions. Under mounting political pressure, several insulin manufacturers preemptively cut list prices in 2023, effectively aligning with the $35/month Medicare cap and extending similar limits to commercial markets. These voluntary reductions on a handful of high-visibility products appeared calculated to defuse criticism and forestall more aggressive government intervention.

Drug pricing has emerged as a rare bipartisan flashpoint. Companies are complying under protest with Medicare negotiations, absorbing near-term financial impacts while waging aggressive campaigns against policies they view as existential threats to their business model.

INDUSTRY WARNINGS AND STRATEGIC ADAPTATION

The industry's broader narrative centers on long-term consequences. Executives routinely warn that price negotiations and controls will stifle innovation, reducing the pipeline of new therapies for future patients[13][14]. Independent experts remain divided on these claims. Some analyses suggest the innovation impact may be modest, with research indicating the industry's warnings are likely overstated[15].

The true effects will emerge over time: Will companies significantly curtail R&D investment, or will they adapt by prioritizing products that can still command premium pricing, such as orphan drugs, biologics, and breakthrough therapies? Early signals suggest adaptation rather than retreat. Many large pharmaceutical firms have assured investors that initial Medicare price cuts are manageable. In earnings calls, several CEOs have downplayed the immediate financial impact and described portfolio adjustments already underway[16].

Yet the industry is hardly acquiescing. Continued legal challenges and aggressive lobbying campaigns reveal a multi-front strategy to contain these pricing measures. The posture is one of managed compliance paired with determined resistance by accepting some constraints while fighting to limit their scope and precedent.

How Pricing Reforms Are Changing the Game

MARKET ACCESS AND REIMBURSEMENT IMPLICATIONS

From a market access and reimbursement perspective, the evolving drug pricing framework is altering incentives and decision-making for payers, providers, patients, and manufacturers. A primary goal of these reforms is improving patient access to medications by reducing cost barriers. The Medicare negotiation program and Part D redesign in the IRA directly address patient out-of-pocket spending. Starting in 2025, once a Medicare beneficiary has paid $2,000 in a year for prescriptions, they pay nothing further, providing relief for patients on costly drugs like cancer therapies or lifelong treatments for chronic illness. This cap means therapies that previously bankrupted some seniors are now within reach, shifting more of the cost burden to Medicare and insurers.

The IRA also recalibrated who pays those remaining costs. Previously, Medicare bore 80% of catastrophic drug costs; now Part D insurers and drug manufacturers must absorb a larger share through mechanisms like a new 20% manufacturer discount above the out-of-pocket cap. Payers (insurers and PBMs), in turn, may respond by managing utilization more tightly for ultra-expensive drugs, since they have more skin in the game under the new cost-sharing structure. We might see increased prior authorizations or formulary management for high-cost drugs, though for drugs with negotiated prices, the requirement to cover them limits the ability to exclude or restrict access.

Exhibit 4: Pricing Strategy Considerations

For drug manufacturers, these changes force a rethinking of pricing strategies across the product life cycle.
Key implications include:

Lifecycle planning around negotiation
Small-molecule drugs face negotiation eligibility after 9 years on the market (vs. 13 years for biologics), prompting speculation that firms may adjust product lifecycles to avoid negotiation.

Moderating price increases
Inflation-indexed rebate penalties in Medicare now discourage the large annual price hikes that were once routine. Hikes must be confined to private markets (subject to scrutiny) where these caps don't apply.

High launch pricing ("front-loading")
Some companies might set steep initial launch prices to maximize early revenue before a potential Medicare price cut kicks in.

R&D portfolio shifts
The IRA's structure is subtly steering investment priorities. Biologic drugs, with a 13-year runway before price negotiation, and orphan drugs that remain exempt from negotiation, have become relatively de-risked.

SHIFTING REIMBURSEMENT DYNAMICS

Reimbursement dynamics are also changing across public programs. In Medicare, once a drug has a negotiated MFP, that price applies across Part D plans (and potentially Part B for physician-administered drugs), simplifying the reimbursement landscape. There is a built-in incentive for physicians and pharmacies to utilize negotiated drugs because their patients benefit from lower cost-sharing and plans cannot drop those drugs from coverage.

Collectively, the pricing paradigm is shifting from an era of price maximization to one of value defense. Manufacturers must now justify their prices under greater scrutiny, rather than relying on unrestricted hikes.

Medicaid already had strict rebate mechanisms guaranteeing it the "best price" and mandatory discounts, but recent federal proposals have sought even deeper concessions. The White House's 2025 push floated requiring that Medicaid patients get the lowest price available globally[10]. If such an "international reference" policy were ever implemented, it would dramatically cut Medicaid drug spending but also force manufacturers to reconsider charging more in the U.S. than elsewhere, potentially triggering a realignment of global pricing.

COMMERCIAL MARKET SPILLOVER EFFECTS

In the private sector, employers and insurers are watching these Medicare changes closely. Negotiated Medicare prices do not automatically apply to commercial plans, but they set reference points. Large private purchasers will likely begin demanding similar discounts for their populations, especially if evidence grows that certain drugs are overpriced relative to their therapeutic value.

We may also see expanded use of value-based pricing arrangements where payment for a drug is tied to patient outcomes, as a way for industry to justify high prices amid skepticism. Already, for some ultra-expensive gene therapies, companies have entered outcomes-based contracts (rebating payers if the treatment fails to achieve expected results) and installment payment plans to spread costs. These innovative reimbursement models could become more common as payers seek assurance of value for money and manufacturers aim to preserve access for breakthrough treatments under tighter budget constraints.

THE EMERGING PARADIGM

The market access and reimbursement environment is moving toward a model of greater cost control and accountability. Patients should see better affordability due to caps and negotiated lower prices on key drugs, which could improve medication adherence and health outcomes. The healthcare system is attempting to balance encouraging pharmaceutical innovation while preventing prices from straining public budgets and patient wallets. This delicate balance is especially evident in how current policies treat rare disease drugs versus more common drugs, as we examine next.

Balancing Rare Diseases and National Priorities

A key tension in drug pricing reform is how to support innovation for rare diseases while addressing the high costs of drugs for common conditions that drive the bulk of healthcare spending. Recent policy changes explicitly recognize this balance.

UNINTENDED CONSEQUENCES: ORIGINAL ORPHAN DRUG EXCLUSION

When the IRA was first enacted, it contained a limited "orphan drug exclusion": any drug approved only for a single rare disease indication would be exempt from Medicare price negotiation[18], as long as the drug had no other approved uses. This carve-out aimed to reassure manufacturers that developing a therapy for a tiny patient pool wouldn't lead to forced price cuts. However, the exemption was narrow—if an orphan drug later gained FDA approval for a second rare disease or any common disease, it would lose protection and become eligible for negotiation after the usual 9-year (small molecule) or 13-year (biologic) window.

Critics warned this created a perverse disincentive: companies might avoid pursuing additional rare disease indications for an already-approved orphan drug, fearing that expanding beyond "one rare use" would trigger negotiation eligibility. After the IRA passed in 2022, some rare disease drugmakers indicated they were rethinking or halting plans to expand indications, worried they couldn't recoup development costs if negotiations loomed.

Data from the first year post-IRA showed a nearly 50% drop in second orphan drug designations—the share of orphan drugs obtaining a follow-on rare indication fell sharply after 2022[19].

This early evidence of a chilling effect alarmed patient advocates and policymakers. In October 2022, Alnylam Pharmaceuticals canceled a planned Phase III trial of its drug vutrisiran in a rare eye disease, explicitly citing the IRA's rules—adding a new orphan use would have meant losing the drug's exemption from Medicare negotiation and potential profits[20].

CONGRESSIONAL RESPONSE: BROADENING THE EXCLUSION

In response, lawmakers moved to strengthen protections for orphan drugs. In mid-2025, Congress passed an amendment as part of a broader budget act (nicknamed the "One Big Beautiful Bill Act") that broadened the orphan drug exclusion[21]. Under the revised rules, a drug with one or more orphan designations for different rare diseases now remains exempt from Medicare price negotiations as long as it has no approved uses outside of rare diseases[21].

Under the revised rules, a drug with one or more orphan designations for different rare diseases now remains exempt from Medicare price negotiations as long as it has no approved uses outside of rare diseases[21]. A therapy can be approved for multiple rare disorders and still maintain complete exemption from government price-setting, until it ventures into a non-orphan indication.

Additionally, the law adjusted the timing: the negotiation "clock" for an orphan drug will not start until the drug obtains a non-orphan approval[22]. Previously, the countdown began at first approval even if that was for an orphan use; now, a drug that remains in the rare disease realm could theoretically stay exempt indefinitely. Only when it gains a non-orphan approval would the standard timeline to negotiation begin[23].

Exhibit 5: Drugs Selected for Price Negotiation

10 Medicare Part D Drugs Selected for Price Negotiation for 2026

The selected drugs include drugs used to treat cancer, diabetes, blood clots, asthma and COPD, and rheumatoid arthritis.

Drug name	Manufacturer	Used for
Eliquis	Bristol Myers Squibb	Anticoagulant
Enbrel	Amgen	Rheumatoid arthritis
Entresto	Novartis Pharmaceuticals Corp.	Heart failure
Farxiga	AstraZeneca	Diabetes, heart failure, chronic kidney disease
Fiasp	Novo Nordisk	Diabetes
Imbruvica	Pharmacyclics	Leukemia, lymphoma
Januvia	Merck	Type 2 diabetes
Jardiance	Boehringer Ingelheim	Type 2 diabetes, heart failure
Stelara	Janssen Biotech	Psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis
Xarelto	Janssen	Anticoagulant

Source: CMS 2023

These changes were celebrated by the rare disease community and small biotech companies. Pharmaceutical firms focused on rare conditions gained a "fresh sense of direction"—many are now reactivating or expanding rare indication research programs that were on hold. The clear intent from Congress was to remove disincentives for orphan drug development, signaling that fostering treatments for rare diseases remains a national priority alongside cost containment[24]. Legal and industry analysts noted this creates a pro-innovation incentive that may spur greater investment and could boost the valuation of biotechs with multiple rare-disease programs, now that they can pursue those uses without an automatic Medicare price cut looming[24].

Drug pricing reform is not one-size-fits-all. Policymakers are targeting high-cost drugs for common diseases to yield broad savings and patient benefits, while protecting rare disease drugs to preserve innovation incentives. The result is a nuanced approach that seeks to rein in overall drug spending without stifling the development of treatments for diseases that affect small populations.

TARGETING HIGH-IMPACT DRUGS FOR COMMON CONDITIONS

Meanwhile, the drugs being targeted for Medicare negotiation reflect national public health priorities; specifically tackling the costs of medications millions of Americans rely on for prevalent diseases. The initial batch of Medicare-negotiated drugs predominantly treats widespread chronic conditions like Type 2 diabetes, heart disease, blood clots, and autoimmune disorders. These are areas where high drug prices have strained both household budgets and Medicare's finances.

By focusing on drugs that are "costliest and most commonly used"—popular diabetes and anticoagulant medications that each serve hundreds of thousands or millions of patients—the government aims for maximum impact in savings and relief. This is a strategic choice: the national priorities in drug pricing reform are therapies that drive the bulk of spending and often create significant patient out-of-pocket burden in common diseases. Lowering the cost of insulin or anticoagulants, for instance, aligns with broader public health goals of improving adherence to essential medications, thereby reducing downstream complications like heart attacks, strokes, and diabetic emergencies.

In contrast, ultra-expensive drugs for rare diseases, while individually very costly, contribute far less to overall spending simply because patient numbers are small. The policy calculus has essentially been: pursue savings on big-ticket, widely-used drugs while shielding niche rare disease drugs to continue encouraging medical breakthroughs. This balance is politically and ethically delicate, attempting to ensure that cost containment efforts "do no harm" to rare disease patients and innovation.

POTENTIAL DOWNSIDES AND FUTURE CHALLENGES

Some experts note potential downsides in this balancing act. With generous exclusions in place, a pharmaceutical company could conceivably keep a drug's price extremely high under the orphan umbrella, knowing it won't be subject to negotiation as long as it avoids larger indications. This raises questions about the affordability of rare disease therapies for payers, including Medicaid and private insurers, which still must pay those high prices. Policymakers may need to monitor whether any abuse of the orphan exclusion occurs—for example, intentionally fragmenting diseases into separate small indications to skirt negotiation.

The expanded orphan carve-out will also have a real cost: by forgoing negotiation on more drugs, the government is accepting higher Medicare spending in exchange for bolstering innovation. One estimate put the cost of broadening these exemptions at several billion dollars in lost savings over time. Policymakers are deliberately giving up some short-term savings in hopes of longer-term benefits in new cures. This trade-off will surely be revisited in the future as we see how many rare disease drugs come to market—and at what prices. The hope is that robust competition via alternative therapies or eventually generics and biosimilars will help moderate orphan drug prices organically, since formal price negotiation won't apply.

Exhibit 6: Drug Pricing Priorities

This visual illustrates the bifurcated U.S. drug pricing approach: widely used, high-cost drugs like insulin and Eliquis face Medicare price negotiation, while rare disease therapies like Zolgensma receive exemptions to preserve innovation incentives. This strategy deliberately reduces systemic costs without undermining rare disease R&D.

Strategic Implications for Market Leaders

Pricing power is no longer guaranteed. Those who align value, policy, and access will shape the next era of pharmaceutical innovation.

ACCESS, HEOR, AND POLICY TEAMS

The U.S. pricing environment has become a policy-driven access framework. For market access, HEOR, and policy leaders, the Inflation Reduction Act, alongside mounting regulatory pressure and payer scrutiny, means value communication must begin earlier and carry more weight across the product lifecycle.

What's Required Now:

- **Integrated evidence planning:** HEOR and access teams must collaborate earlier in development to align clinical and economic evidence with policy and payer needs.
- **Real-time adaptability:** As CMS pricing decisions, FTC investigations, and state-level reforms evolve, access leaders must proactively scenario-plan for both launch and in-market products.
- **Elevated policy fluency:** Understanding the IRA, orphan exemptions, negotiation timelines, and post-market obligations is now essential for informed payer engagement.

DRUG MANUFACTURERS

The IRA has reset expectations for pricing power in the U.S. Manufacturers are entering an era where value must be demonstrated early, defended continuously, and adapted to a fast-changing policy environment. Pricing strategies based on back-end rebates and long revenue tails must give way to precision planning, earlier negotiation readiness, and evidence-backed access.

What leading manufacturers should prioritize:

- **Portfolio recalibration:** Biologics and orphan indications offer longer price protection under IRA timelines. Small-molecule strategies require rethinking launch sequencing and investment allocation.
- **Value strategy as core capability:** Commercial success will hinge on robust HEOR, real-world evidence, and contracting models aligned with therapeutic and economic outcomes.
- **Policy engagement as a growth lever:** Proactive collaboration with regulators and policymakers will be essential for shaping sustainable pricing models and securing future market opportunity.

Leading companies are responding by integrating policy, pricing, and evidence planning into their core commercial strategy, treating market access as a driver of competitive advantage, not an afterthought.

Call to Action:

Navigating the IRA requires earlier decisions, tighter alignment, and continuous value defense. We call on pharmaceutical leaders to:

Priority 1:
Integrate Evidence Planning Now

BUILD HEOR INTO STRATEGY

HEOR and market access can no longer be Phase III activities. Winning strategies require:

Evidence Planning
Evidence generation aligned with payer needs from Phase II forward

Value Story
Early engagement with health economics to build comparative value stories

Internal Alignment
Cross-functional teams (R&D, Medical, Commercial, Access) aligned on value proposition

Priority 2:
Build Policy Fluency Across Leadership

SCENARIO PLAN PROACTIVELY

Every commercial decision now requires policy assessment:

Understanding the Rules
How do IRA negotiation timelines affect our indication sequencing?

Preparing for Multiple Outcomes
What orphan exemption strategies optimize our rare disease portfolio?

Assessing Vulnerabilities
Where are we vulnerable to state-level reforms or FTC scrutiny?

Priority 3:
Prepare for Value Defense

DEMONSTRATE ONGOING VALUE

The era of "set and forget" pricing is over. Success requires:

Real-World Evidence
Develop RWE programs that prove sustained therapeutic and economic value

Outcomes-Based Contracting
Build capabilities for value-based agreements and risk-sharing models

Commercial Transformation
Train commercial teams to communicate value across therapeutic, economic, and patient outcomes

Conclusions

Summary

U.S. drug pricing has entered a new era of negotiation, regulation, and value scrutiny.

The IRA formalizes a shift toward negotiated, value-based pricing, introducing Medicare negotiation while carefully protecting rare disease innovation through targeted exemptions.

For pharmaceutical leaders, this transformed landscape demands precision planning, earlier evidence generation, and proactive policy engagement. Companies that integrate pricing strategy, HEOR capabilities, and regulatory fluency into core operations will be positioned to lead.

The winners in this environment will build strategic infrastructure to navigate a regulated, value-driven future.

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