How MFN is rewriting global drug launch strategy

By Joe Stevens, Jon Roffman, Cody Powers, Howard Deutsch and Julia Duncan

What biopharma leaders need to know about MFN drug pricing

The Trump administration's Most Favored Nation (MFN) drug pricing agenda seeks to narrow the large price differential between drugs sold in the U.S. and other developed countries. U.S.-branded drug prices are approximately three times higher than comparable Organisation for Economic Co-operation and Development (OECD) nations, even after accounting for rebates. The U.S. also generates more than half of global pharma sales, making any reduction in U.S. pricing an outsized event for global biopharma economics. What began as a May 2025 executive order (EO) is moving toward implementation through several programs that seek to harmonize prices between the U.S. and other developed countries.

The programs include:

- **GENEROUS:** Generating Cost Reductions for U.S. **Medicaid**
- **GLOBE:** Global Benchmark for Efficient Drug Pricing for **Medicare Part B**
- **GUARD:** Guarding U.S. Medicare Against Rising Drug Costs for **Medicare Part D**

In addition, the government has launched TrumpRx, a direct-to-patient channel making MFN-linked prices visible outside traditional coverage.

As of May 2026, 17 manufacturers (covering approximately 86% of the branded drug market) have signed voluntary agreements, the two mandatory Medicare rules await finalization, and GENEROUS implementation is underway. On May 5, 2026, the White House published a formal savings analysis projecting $529 billion in savings over 10 years from prospective MFN pricing across all markets, including commercial and employer-sponsored insurance and $64.3 billion in Medicaid savings.

For biopharma, MFN creates a structural linkage between U.S. and ex-U.S. pricing that fundamentally alters calculations of launch sequencing, global net price governance and expected return on investment. However, uncertainty remains. The final rule on GLOBE and GUARD has yet to be determined. Deadlines for GENEROUS have been extended. Legal challenges are anticipated. Even Congress is unaware of the exact terms agreed to by the major drug manufacturers.

The impact of this policy and its surrounding uncertainties has been multifaceted: U.S.-only launches, delayed launches in Europe, PBM disintermediation and multiyear "wait it out" strategies. Such actions would have been unthinkable by drug manufacturers two years ago. But the world has shifted with the rise of MFN pricing and policies, and manufacturers must adapt to this new reality.

The new reality for manufacturers: A broader, more aggressive MFN mandate

MFN drug pricing is not a new topic. In September 2020, during the Trump administration's first term, the president issued an EO directing HHS to test a Medicare Part B payment model at MFN prices (see Figure 1 for the full timeline). That effort was narrow in scope—limited to Part B—and was blocked within weeks by federal courts for failing to follow proper regulatory procedures. The Biden administration subsequently withdrew the rule.

The May 2025 EO revives the same core objective, but with a broader architecture and greater procedural adherence. At the order signing, the goal was framed bluntly: "We're going to equalize [prices] … We're going to pay what Europe's going to pay." The EO argues that Americans should not be forced to subsidize lower prices in other developed countries and must have access to the low prices received elsewhere.

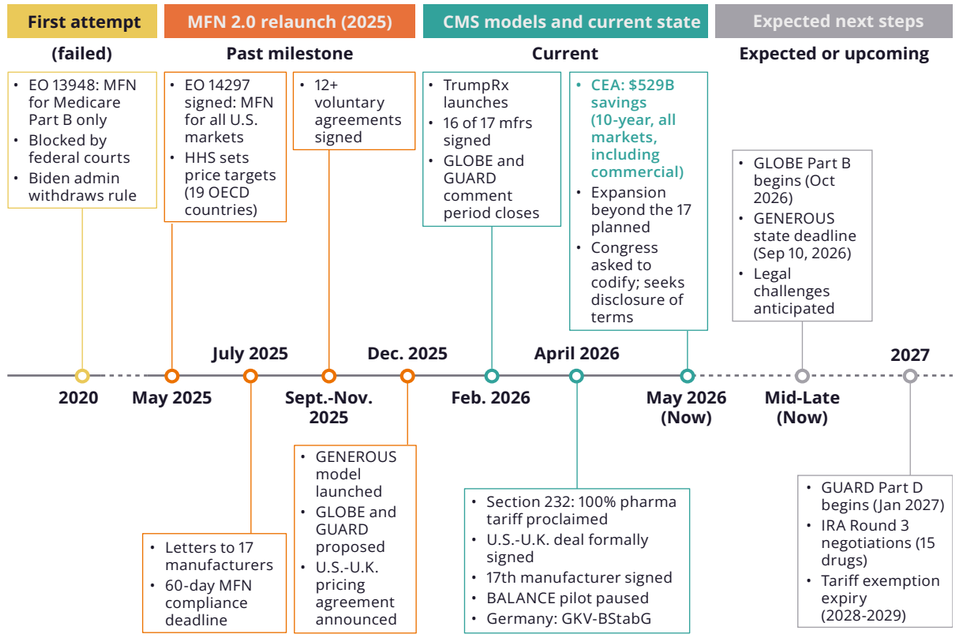
The current approach goes beyond the 2020 Part B experiment. It begins with a broader federal program and patient-affordability focus across Medicare, Medicaid and cash-pay channels. It also expanded commercial exposure through the July 2025 manufacturer letters, which sought MFN guarantees for new launches across these channels.

While the government is pursuing MFN for Medicare and Medicaid through federal programs that impact reimbursement and rebates, commercial MFN is being pursued through voluntary manufacturer commitments rather than a dedicated payment model, leaving the enforcement mechanism less clearly defined. The approach deploys multiple implementation channels, uses Section 232 tariffs as an enforcement backstop and is working to implement its core programs through rulemaking rather than requiring congressional approval.

The industry responded with over $500 billion in committed U.S. investments over the next decade and secret "MFN deals" with all 17 manufacturers. The combination of broader scope, procedural compliance, trade enforcement and a voluntary first engagement strategy marks a fundamentally different approach from 2020.

FIGURE 1:

The MFN policy evolution timeline



IRA = Inflation Reduction Act. Sources: CMS, HHS, White House, other secondary sources.

How is MFN being implemented?

MFN is being implemented through overlapping policy and market levers rather than a single reimbursement rule. Voluntary manufacturer agreements create the first layer of commitments, tariffs add pressure to align U.S. and international pricing, CMS programs translate MFN into Medicaid and Medicare mechanisms, and TrumpRx creates a consumer-facing cash-pay channel that makes MFN-linked pricing more visible.

The 17 voluntary manufacturer agreements

As of May 2026, the administration had announced voluntary MFN agreements with 17 manufacturers, covering a substantial share of the U.S.-branded prescription drug market. Public statements indicate that these agreements generally link Medicaid MFN access, new-launch pricing commitments, TrumpRx and direct-to-patient discounts, and U.S. manufacturing and tariff-relief arrangements.

These 17 may also not be the last such agreements. The administration's May 2026 Council of Economic Advisers (CEA) report confirms it expects to expand agreements to most sole-source

branded drug manufacturers. Some manufacturers have also received or negotiated FDA Commissioner's National Priority Voucher Program (CNPV), a pilot mechanism intended to shorten review timelines from the standard 10 to 12 months to roughly one to two months for selected applications in exchange for their commitments.

Company	CNPV granted?	CNPV granted date	Drugs receiving accelerated review via CNPV	Approval
Pfizer	No			
AstraZeneca	No			
EMD Serono	Yes	16-Oct-25	Pergoveris (women's health)	Not approved yet
Novo Nordisk	Yes	6-Nov-25	Wegovy HD* (metabolic disease)	19-Mar-26
Eli Lilly	Yes	6-Nov-25	Foundayo* (metabolic disease)	1-Apr-26
Amgen	No			
Bristol Myers Squibb	No			
Boehringer Ingelheim	Yes	6-Nov-25	Hernexeos* (oncology)	26-Feb-26
Roche	No			
Gilead	No			
GSK	Yes	6-Nov-25	Jemperli (oncology)	Not approved yet
Merck & Co.	Yes	19-Dec-25	Enlicitide decanoate (cardiovascular); Sacituzumab tirumotecan (oncology)	Not approved yet
Novartis	No			
Sanofi	Yes	16-Oct-25	Tzield (endocrine)	Not approved yet*
Johnson & Johnson	Yes	6-Nov-25; 15-Dec-25	Sirturo (infectious disease); Tecvayli plus Darzalex Faspro* (oncology)	Not approved yet (Sirturo); 5-Mar-26 (Tecvayli plus Darzalex Faspro)
AbbVie	No			
Regeneron	Yes	16-Oct-25	Otarmeni* (neurology)	23-Apr-26

*As of May 2026, Sanofi has asked to pull Tzield from FDA's CNPV program. Note: This table reflects CNPVs granted to the 17 MFN signatory manufacturers only. As of May 2026, the FDA has awarded more than 20 CNPVs through the broader pilot program.

Industry executives have signaled that engagement was driven less by enthusiasm than by fear of the alternative. Several pharma leaders have cautioned investors that the impact of their agreements is "not immaterial," while others have warned of "difficult decisions" ahead on how to launch and price globally. A significant point of contention is transparency.

The agreements contain provisions barring the disclosure of terms. On March 5, 2026, ranking members of four House and Senate committees wrote a joint letter to President Trump demanding unredacted copies—noting that Congress has been asked to support deals it has not been allowed to review. As of June 2026, agreement terms remain confidential.

Tariffs an incentive to change pricing policies abroad

Tariffs are intended to become the coercive backstop that gives the current MFN framework more enforcement power than its 2020 predecessor. The tariff structure initially created country-level ambiguity, particularly for the EU, where officials questioned whether prior U.S.-EU commitments would cap pharma-related Section 232 duties or whether additional sector-specific tariffs could apply. The April 2026 Section 232 proclamation has since clarified the framework: Patented pharmaceutical imports and associated pharmaceutical ingredients face a default 100% tariff, with preferential country-level rates of 15% for the EU, Japan, South Korea, Switzerland and Liechtenstein and 10% for the U.K.

At the company level, manufacturers with approved onshoring plans receive a 20% rate, while those with both onshoring and MFN pricing agreements can qualify for a zero tariff through January 20, 2029 (where more than one rate applies, the lowest prevails). Generic pharmaceuticals and biosimilars are exempt for now, while orphan drugs are exempt where all approved indications are orphan-designated. The tariffs take effect July 31, 2026, for the 17 signatory companies and September 29, 2026, for all others. On May 13, 2026, the Department of Commerce published formal procedures for companies to apply for onshoring agreements, with applications due June 12, 2026, creating an immediate action deadline for manufacturers seeking tariff relief.

The U.S.-U.K. arrangement illustrates this logic, with tariff relief tied to U.K. commitments to increase spending on new medicines, raise net prices and adjust access and pricing mechanisms. Additionally, the National Institute for Health and Care Excellence's (NICE) threshold increase (£20,000-£30,000 to £25,000-£35,000 per QALY) is expected to result in three to five additional medicines or indications recommended per year.

While these have been lauded as positive improvements in the U.S., the durability of tariffs as an enforcement mechanism is uncertain. In February 2026, the Supreme Court ruled that the administration could not impose broad tariffs under the International Emergency Economic Powers Act—the authority originally used for the "reciprocal tariffs." The administration pivoted to Section 122 of the Trade Act of 1974, but that authority is temporary (150 days, max 15%) and faces its own legal challenges. The pharma-specific tariffs rest on Section 232 (national security), which is legally distinct and was not addressed by the court.

But the ruling underscores that tariff-based enforcement is subject to judicial constraints that could evolve. Thus, whether trade-backed bargaining can be sustained as a long-term pillar of MFN remains an open question.

At the same time as the U.K. agreement, Germany is moving in the opposite direction. Its April 2026 GKV-BStabG package introduces a dynamic manufacturer rebate and extends the price moratorium, changes which are expected to push rebates paid by manufacturers above the current 7% level and which will reduce, not raise, net pharmaceutical spending and revenue for drug manufacturers. In addition to being the opposite result that the U.S. hoped to achieve with MFN, industry executives have warned that Europe may need a "complete rethink" of its reimbursement systems, while describing recent German reforms as moving "in the wrong direction."

New reimbursement policy in the U.S.: GENEROUS, GLOBE and GUARD

Alongside the voluntary agreements, MFN is being operationalized through three CMS programs. Each targets a different segment of government insurance and differs in regulatory maturity, enforcement and price anchoring. Together, GENEROUS, GLOBE and GUARD translate MFN from a broad pricing principle into three payment-specific levers across Medicaid, Medicare Part B and Medicare Part D (see Table 1 for a comparison of the three models).

GENEROUS (Medicaid) is a voluntary, five-year pilot launched in January 2026. It enables manufacturers to offer MFN-aligned supplemental rebates to state Medicaid programs, benchmarked to the second-lowest net price from eight reference countries adjusted for GDP per capita. Critically, these supplemental rebates do not count toward Medicaid Best Price, avoiding additional rebate liability—a design choice intended to minimize disruption and encourage participation. The program also **requires manufacturers to disclose net prices**, a significant step given that no existing dataset captures international net pricing with good coverage and accuracy. The application deadline for manufacturers has been extended to June 11, 2026, with states having until September 10, 2026, to apply.

GLOBE and GUARD are the proposed mandatory Medicare counterparts. GLOBE would modify the Part B inflation rebate calculation for selected high-spend, single-source drugs and biologics using international benchmarks, while GUARD would create an alternative Part D rebate calculation when U.S. prices exceed prices in economically comparable countries. Neither model directly sets U.S. price based on foreign prices and instead operates through rebate or payment adjustments rather than classic price controls. However, both increase pressure on manufacturers by tying U.S. government payment exposure to international price comparisons.

Similar to GENEROUS, a key feature across the architecture is the push toward net-price disclosure. Under GLOBE and GUARD, manufacturers can choose between a CMS-calculated benchmark based on the lowest publicly available list price across reference countries (Method I) or voluntarily submitting their own international net prices to receive a more favorable volume-weighted average benchmark with a higher adjustment factor (Method II).

Since the final benchmark is the higher of the two approaches, withholding data could only hurt, making transparency itself part of the enforcement strategy. The comment period closed in February 2026, with final rules expected mid-to-late 2026; legal challenges are also likely given the scale of change.

TABLE 1:

MFN pricing levers at a glance

Program	GENEROUS	GLOBE	GUARD
Channel type	Medicaid-linked supplemental pathway	Medicare Part B payment model	Medicare Part D payment model
Coverage	Medicaid (MDRP)	Medicare Part B (clinic-administered); 25% of beneficiaries	Medicare Part D (retail pharmacy); 25% of beneficiaries
Participation	Active/voluntary	Proposed/mandatory (all qualifying manufacturers)	Proposed/mandatory (all qualifying manufacturers)
MFN reference	Second lowest country net price, adjusted for GDP per capita based on 8* MFN benchmark countries	Lowest country list price (third-party data) or volume-weighted average net price (if manufacturer discloses);19 OECD countries**	Lowest country list price (third-party data) or volume-weighted average net price (if manufacturer discloses); 19 OECD countries**
Eligible drugs	Covered outpatient drugs in MDRP	Single-source drugs and sole-source biologics; ≥$100M spend; 7 specified categories; excludes drugs subject to IRA MFP (product exclusion), products lacking ASP (product exclusion), 340B units (unit exclusion) and discarded units (unit exclusion)	Sole-source drugs included/ invoiced under the Part D Drug Inflation Rebate Program, with gross Part D spend > $69M (2027); threshold increases annually based on CPI-U; limited to 17 specified categories; excludes IRA MFP drugs, generics, biosimilars and 340B units
Start date	Rolling from Jan. 1, 2026 (5-yr)	Oct. 1, 2026 (5-yr)	Jan. 1, 2027 (5-yr)
Est. GTN impact	Depends on the current level of rebating	~4% reduction to total GTN**	~3% reduction to total GTN**
Status (May 2026)	Active pilot. State deadline: Sept. 2026.	Finalization expected Q3 2026. Effective date: Oct. 2026.	Finalization expected Q3 or Q4 2026. Effective date: Jan. 2027

*MFN benchmark countries include the U.K., France, Germany, Italy, Canada, Japan, Denmark and Switzerland; ** on-U.S. OECD members meeting GDP thresholds (≥60% U.S. GDP/cap; ≥$400B GDP): Australia, Austria, Belgium, Canada, Czechia, Denmark, France, Germany, Ireland, Israel, Italy, Japan, Netherlands, Norway, South Korea, Spain, Sweden, Switzerland and the U.K. Based on: ~98% Part B enrollment × ~25% covered lives in model scope × ~75% expected MFN price reduction for GLOBE; ~81% Part D enrollment × ~25% in model scope × ~75% MFN price reduction for GUARD. Assumes insurance distribution of the indicated population is in line with the U.S. population. GLOBE therapeutic categories (7): antigout agents, antineoplastics, blood products and modifiers, central nervous system agents, immunological agents, metabolic bone disease agents, ophthalmic agents; GUARD therapeutic categories (17): analgesics, anticonvulsants, antidepressants, antimigraine agents, antineoplastics, antipsychotics, antivirals, bipolar agents, blood glucose regulators, cardiovascular agents, central nervous system agents, gastrointestinal agents, genetic or enzyme or protein disorder: replacement or modifiers or treatment, immunological agents, metabolic bone disease agents, ophthalmic agents, respiratory tract and pulmonary agents.

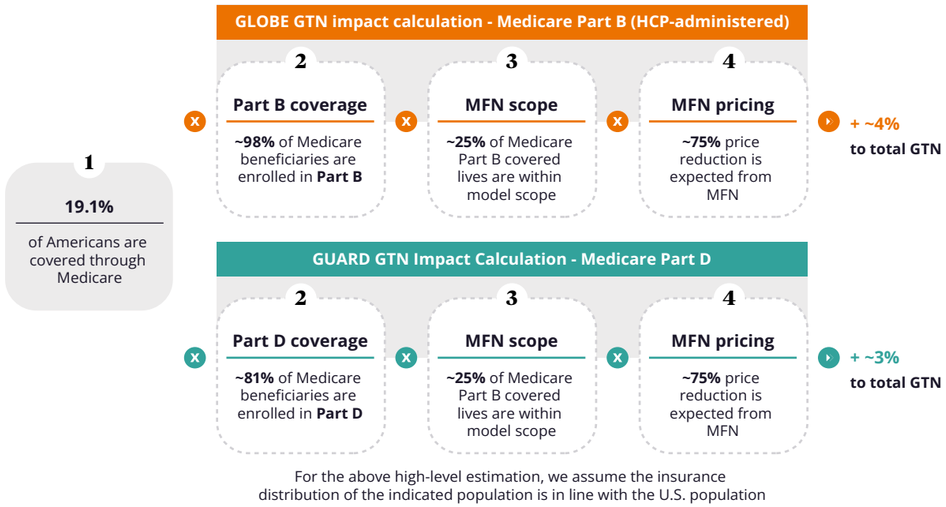
Importantly, MFN does not create a single universal drug list across these reimbursement models. Product-level exposure is determined by payer channel, drug characteristics and participation criteria: GENEROUS applies through Medicaid and depends on manufacturer and state participation; GLOBE applies to qualifying high-spend Medicare Part B drugs; and GUARD applies to qualifying Medicare Part D drugs. As a result, not every product falls within the scope of every CMS model.

Eligibility depends on channel, spend thresholds and therapeutic category. For the 17 manufacturers that signed voluntary agreements, the extent to which inline products versus pipeline assets are covered appears to vary by agreement, terms remain confidential, and not all portfolio products may be uniformly exposed. For products that do fall within the model scope, the aggregate GTN impact may be more contained than the headline price reductions suggest.

To illustrate: GLOBE and GUARD each cover ~25% of Medicare beneficiaries, and if the international benchmark results in a ~75% price reduction for qualifying products, the blended impact on a manufacturer's total GTN would be in the range of around 3% to 4% additional GTN erosion. However, this average masks significant variation by product type and life cycle stage. Drug types with the highest exposure include oncology monoclonal antibodies, infused and injected Part B biologics, and high-spend metabolic injectables for diabetes—driven by large patient populations, high public payer reliance and wide U.S.-to-ex-U.S. price differentials. Orphan drugs present a mixed picture depending on Medicare population size, while pediatric products and gene therapies face low direct exposure.

FIGURE 2:

The estimated impact of GLOBE and GUARD on gross-to-net, in aggregate



For the above high-level estimation, we assume the insurance distribution of the indicated population is in line with the U.S. population

Sources: CMS 2024 Medicare Enrollment; KFF Medicare Advantage 2025; SingleCare Medicare Statistics 2026 (citing CMS); CMS GLOBE and GUARD Proposed Rules (Dec. 2025).

What role does TrumpRx play in MFN drug pricing?

TrumpRx introduces a separate cash-pay affordability layer outside the traditional insurance benefit, connecting patients to direct purchase prescription drug sales with the intention to drive lower prices. Initially launched in February 2026 as a portal connecting patients to manufacturer-discounted branded drugs and coupon-based pharmacy access, TrumpRx.gov was primarily relevant for categories where insurance coverage is often limited or variable, including GLP-1 therapies and fertility medications.

As of June 2026, 15 of the 17 MFN signatory companies have listed products on TrumpRx, with the platform showing 75 branded "presidential deal" medications. It has also expanded into broader cash-price transparency, adding >700 generics through price-comparison and pharmacy partner integrations, including Amazon Pharmacy, GoodRx and Mark Cuban's Cost Plus Drug Company.

However, TrumpRx remains structurally limited. It does not sell medicines directly, largely redirects patients to manufacturer or pharmacy channels, and self-pay purchases generally do not count toward insurance deductibles or out-of-pocket maximums. Because discounts are typically framed against list prices rather than confidential insurer-negotiated net prices, TrumpRx may improve price visibility and access for select cash-pay patients, but it is not a systemic replacement for insurance-based affordability.

Additionally, independent analyses found that many TrumpRx prices remain higher than those in reference countries including Germany, the U.K. and Japan—undermining the administration's claim of offering the world's lowest prices. While it appears that TrumpRx has not yet achieved its goal of bringing MFN prices to every American, it has succeeded in increasing price transparency and awareness of medicine's actual acquisition cost. Its long-term role remains uncertain, but TrumpRx has already made drug acquisition costs more visible outside traditional insurance channels.

What this means for pharma companies

MFN changes the strategic question for manufacturers from "How do we protect U.S. price?" to "How do we optimize launch, access and evidence decisions when U.S. and ex-U.S. prices are increasingly connected?" The implications are not limited to near-term rebate exposure; they extend to launch sequencing, portfolio prioritization, evidence generation, market participation and the commercial attractiveness of reference countries.

The MFN framework introduces challenges for biopharma companies

Uncertainty around future policy remains high. GLOBE and GUARD are still proposed rules. Agreement terms with manufacturers are confidential and legal challenges are anticipated. Companies are building long-term portfolio strategies on a regulatory foundation that is still being laid, and the administration's push to codify agreements into law means the policy window extends beyond the current term.

Most drug manufacturers outside of the 17 that have already signed deals are currently following a "wait and see" approach to how the policy evolves. A recent Q2 2026 BPSI survey shows ~52% (n=904) expect MFN will be watered down, and only 7% expect significant U.S. price drops.

However, the fact remains that launching in Europe, Japan and many other markets now carries direct risk to U.S. pricing. Under MFN, a lower price established in a reference market can anchor U.S. benchmarks. Several pharma leaders have warned of "difficult decisions" on how to launch and price globally. However, delaying a global launch is also risky. Companies that slow or avoid ex-U.S. launches may lose effective patent life, invite political pressure around access and cede opportunity to competitors. For assets with copycat or follow-on competition risk, nonlaunch may create a market vacuum that rivals can fill, potentially weakening both ex-U.S. access and future U.S. pricing strategy.

Finally, MFN exposure is not uniform across the industry. Large pharma with broad Medicare and Medicaid footprints face the most acute near-term pressure. Since all 17 original targets have signed agreements, the question has shifted from whether to engage to how to optimize within what was agreed. Mid- and small-cap companies were not on the original target list but remain exposed. The CEA report confirms the administration intends to expand agreements to most sole-source manufacturers, and the Midsized Biotech Alliance of America has filed legal action against the 100% tariff, arguing that companies with one or two drugs lack the portfolio diversity to absorb revenue compression. For pipeline-driven companies of any size, assets in GLOBE- or GUARD-relevant therapeutic categories carry risk regardless of whether the company has signed an agreement.

How pharma is responding

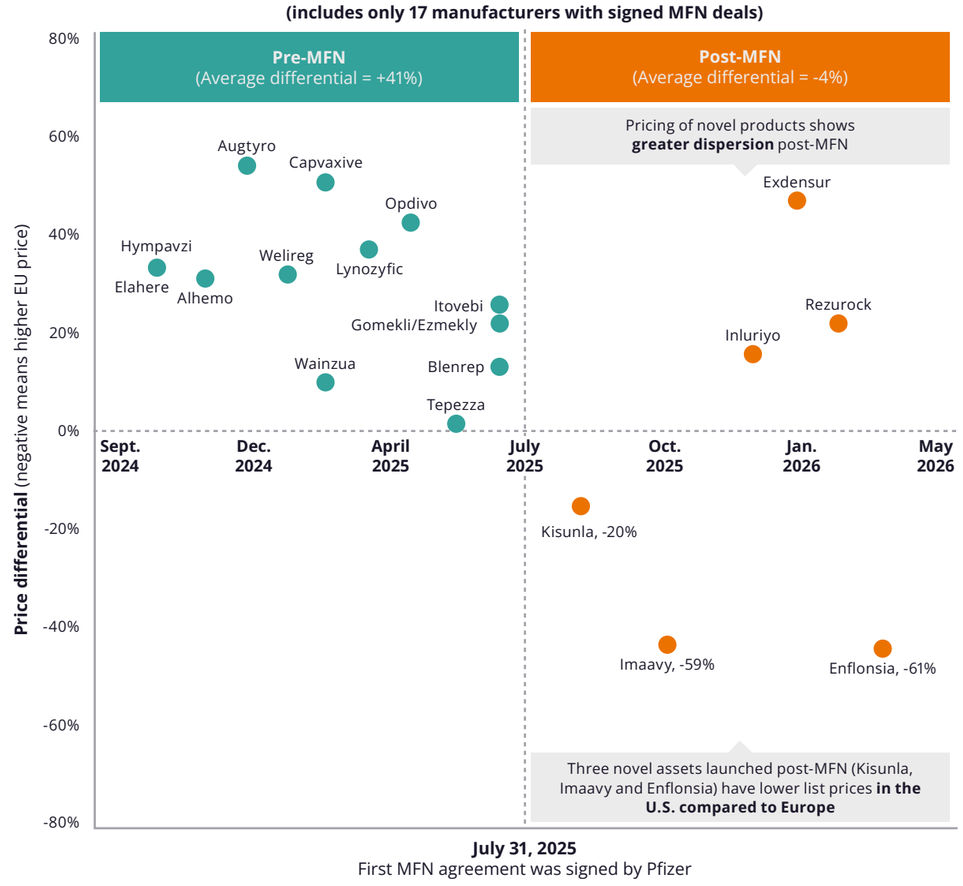
Pharma companies are not responding to MFN with a single playbook. Early actions point to a mix of launch delays, pricing adjustments, market-by-market sequencing decisions and scenario planning as manufacturers try to protect U.S. economics while preserving access and growth outside the U.S.

Reassessing EU launch strategies:
Early signals emerging. Patterns are beginning to surface through selective delays and withdrawals in certain markets, with pricing uncertainty cited as a contributing factor. While there has always been high volatility in the number and timing of international launches, and any change certainly cannot be attributed solely to MFN, the directional pattern is consistent with policy predictions and therefore hard to ignore. ZS analysis of EU and U.K. drug launches across 13 MFN reference countries suggests the pace of launches in Europe may indeed be slowing. Comparing the 13 months post-MFN to the 13 months prior (April 2024 to May 2026), launches in Europe declined 7%, with the U.K. (21%) seeing one of the steepest declines. Second, time-to-launch lengthened by 19% on average across the 13 MFN reference countries. Several upcoming U.S. launches are expected to provide a visible test of how MFN pricing applies in practice, though transparency around specific terms remains limited.

Impact on pricing: Early signs of compression.
A ZS analysis of list price differentials between the U.S. and Europe for novel drugs launched by the 17 MFN signatory companies shows a directional shift, though the post-MFN sample remains small (n=6). The average U.S.-to-EU price differential moved from +41% pre-MFN to -4% post-MFN, a pattern that, while not yet conclusive, does not mirror historical pricing behavior. Three recently launched novel assets that came to market after the first MFN agreement (Kisunla, Imaavy and Enflonsia) actually carry lower list prices in the U.S. than in Europe and all three have so far launched in only a subset of EU countries. The pricing of novel products also shows greater dispersion post-MFN, suggesting companies are navigating new and inconsistent pricing strategies as the policy landscape evolves. The industry will be keenly watching the future launches and EU price trajectory of these products going forward.

FIGURE 3:

The price differentials between novel drug launches in the U.S. and EU, pre and post the first MFN deal



What pharma leaders must do now

MFN is forcing manufacturers to make difficult near-term decisions and think more critically about longer-term pipeline development. Leaders must evaluate launch sequencing, asset-level MFN exposure and evidence needs in that context. Paradoxically, MFN could also represent an opportunity for pharma to disrupt industry norms that have long worked against patient access to innovation in some countries.

Pharma executives should ask three questions:

How should we rethink launch decisions?

In the near term, the conservative strategy would be to delay ex-U.S. launches until there is more clarity around policy impact, but this warrants closer examination. Depending on expected patent life, ex-U.S. launch delays beyond about two to three years would risk assets not hitting peak sales outside the U.S. before LOE while still triggering MFN rebates during the U.S. peak.

Other strategies that have been floated include delaying launch to allow time for more robust evidence generation and taking more thoughtful approaches to launch sequencing, but these strategies will not close the U.S. and ex-U.S. price difference enough to offset the MFN's impact meaningfully. Ironically, the decision may become easier in highly competitive markets if new entrants are expected to significantly erode net price regardless of MFN rebates. As the policy impacts are better understood toward the end of 2026, leaders must decide at the asset level whether to double down on the U.S. or support full global launches that prioritize speed and volume to mitigate the impact of U.S. revenue losses. Taking the middle ground (e.g., delaying or limiting ex-U.S. launches to only certain markets) is a losing strategy in many cases.

How should MFN shape our longer-term pipeline development decisions?

Given the above, leaders should ask early in clinical development if assets can support a global launch and shape clinical programs accordingly. Even when pricing upside exists ex-U.S., health technology assessment (HTA) systems often require stronger evidence packages (e.g., cardiovascular outcomes trials) that are inherently riskier, more expensive and time-consuming to develop, delaying time to market.

For a product that presents strong MFN risk, manufacturers can strategically disinvest from ex-U.S. launches, focusing only on developing evidence that is sufficient for U.S. regulators, payers and HCPs, without worrying if the evidence can support evaluation by strict HTA systems. This extends to decisions such as clinical site selection, which is currently driven in part by markets offering downstream price upside for conducting trials locally. For some assets, a U.S.-only launch may be most appropriate, and manufacturers could then drive a leaner model through clinical development and commercialization.

Interestingly, the converse is also likely to be true. MFN can potentially open up opportunities for late-to-market or me-too assets that might never have gained sufficient market share in a globally homogenous market to justify their development, but now can launch to a wide-open Europe after the leading product launched in the U.S. only to project its price. Regardless, the status quo of "launch everywhere usually in the same order" will be supplanted by an individual optimization of launch strategy and sequence on an asset-by-asset level.

How can we use MFN to challenge the status quo?

MFN emerged from the perception that the U.S. pays substantially more than other countries for the same drugs. But manufacturers also face unfavorable market conditions in many reference countries, and the disruption created by MFN gives the industry an opportunity to address some of those conditions if it is willing to take bolder action.

Pharma has long believed global payer bodies are not built to fully recognize the clinical, economic and societal value of truly transformational drugs, given the rigidity of many HTA systems and increasing budget pressures. Manufacturers should use MFN as a catalyst to engage policymakers and nontraditional access stakeholders in MFN reference countries to reform pricing policies and cocreate new funding pathways (e.g., private insurance, employer contributions). While this has historically been hard for an individual pharma manufacturer to achieve, MFN now provides a strong incentive for the industry to act collectively.

Pharma has long been averse to middlemen like PBMs extracting value from the system and driving large gross-to-net differentials without offering substantial upside to plan sponsors or patients. Recent policy developments like the FTC's settlements with ESI and CVS are progress toward a lower GTN world, and manufacturers should explore ways to further support the shift, helping to partially mitigate the impacts of MFN.

Manufacturers have spent substantial sums on commercializing in MFN reference markets, but these markets have been trending less attractive and now represent a direct threat to U.S. revenues under MFN. There may be opportunities to shift focus and investment to other non-MFN markets like China, Brazil and India to drive additional revenue. While not as high value as the MFN reference markets currently, many of these markets are high growth and strong commercialization in the developing world could offset some of the revenue lost in Europe, while also benefitting patients who may be underserved today.

For biopharma leaders, MFN drug pricing should be treated as a launch strategy, evidence planning and global net price governance issue—not just a U.S. reimbursement policy. MFN has and will continue to force difficult discussions and drive difficult decisions for pharma leaders. Those who succeed will take clear-eyed action and turn this challenge into an opportunity to disrupt industry norms in favor of sustainable patient access to innovation.

The authors would like to thank Divyata Mavanti and Rahul Pathak for their contributions to this article.

About the authors

Joe Stevens leads ZS's healthcare ecosystems practice area, helping companies design and implement organized customer and B2B strategies to adapt to the ever-changing landscape. He is also a member of ZS's ecosystem i-team, an internal task force focused on evaluating the changes in the U.S. healthcare ecosystem and developing innovative solutions to the issues that emerge.

Joe's work focuses on helping pharmaceutical clients develop strategies to communicate innovative product value, set prices that balance financial return with patient access to medicine, and develop impactful programs and services directed at both payers and large provider organizations. Joe is also well versed in global healthcare markets after spending five years in ZS's Tokyo office and conducting significant project work in the EU5, Canada, China and South Korea during his tenure at ZS.

Jon Roffman is the global head of biopharma, leading ZS's thought leadership and partnering with industry leaders to develop strategies that improve patient outcomes worldwide. His previous roles at ZS include the managing principal for ZS's North region, the client service lead for one of ZS's largest global clients and the leader of the oncology practice area.

Cody Powers is a principal in ZS's New York office, where he leads the portfolio and business development practice—helping clients address both "where to play" strategy and inorganic growth challenges. Cody has over 13 years of experience in healthcare and life sciences consulting with companies of all stages and across a range of strategy issues, including corporate and portfolio strategy, business development and licensing and pipeline assessment. Cody has been a featured speaker at leading industry forums, including the BIO International Convention, LSX World Congress and Fierce Biotech events, as well as across major media outlets.

Howard Deutsch leads strategy and transformation at ZS, helping life sciences companies shape go-to-market strategy, drive product growth, improve market access and advance insights through ZS research.

Howard has more than 15 years of experience working with the life sciences industry, including more than a decade in U.S. value and access, an area he led at ZS from 2014 to 2018. Howard has also worked with life sciences companies on a wide array of commercial strategy and execution issues. In addition, he's a frequent author and speaker on the subject of the U.S. healthcare landscape and how changes in the environment are affecting manufacturers.

Julia Duncan is manager in the ZS San Francisco office and is a member of the market access and pricing team. She works at the intersection of U.S. and global market access to help manufacturers define strategies that optimize patient access to innovation.

About ZS

ZS is a management consulting and technology firm that partners with companies to improve life and how we live it. We transform ideas into impact by bringing together data, science, technology and human ingenuity to deliver better outcomes for all. Founded in 1983, ZS has more than 15,000 employees in 40-plus offices worldwide.

Learn more: www.zs.com