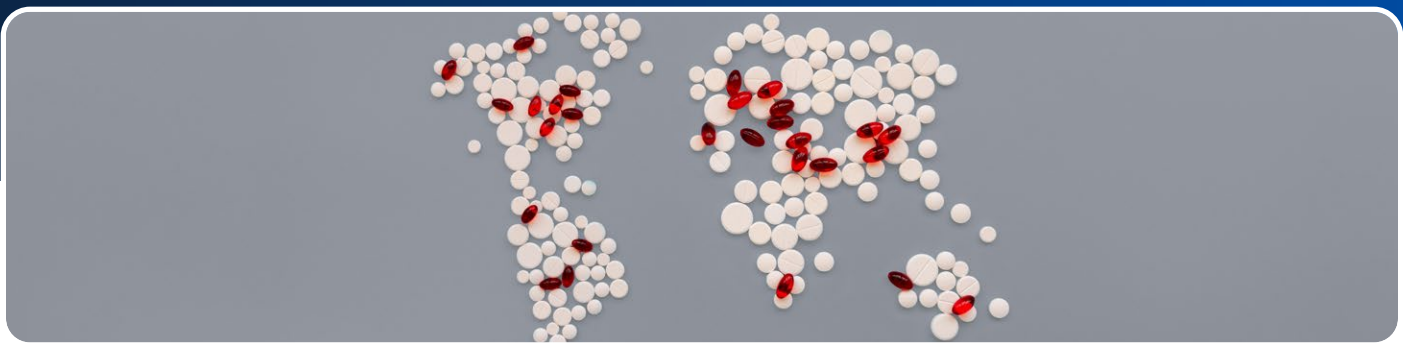
ARTICLE

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Global Pricing Under Pressure: The 90- to 180-Day Most-Favored-Nation Response Roadmap

Navigating U.S. drug pricing reforms and mitigating international spillover risks by leveraging technology

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Executive summary

The article and part 1 of the Global Pricing Under Pressure series, "Building Most-Favored-Nation-Ready Organizations With Technology," established the new operating reality created by the current wave of U.S. Most-Favored-Nation (MFN) pricing reforms. The U.S. market's historical role as the primary engine of global pharmaceutical revenues and profits (approximately 50% of revenues and 75% of profits) is now directly linked to international price benchmarks through three core programs: the voluntary GENEROUS model for Medicaid (currently in active pre-implementation) and the proposed mandatory GLOBE (Medicare Part B) and GUARD (Medicare Part D) models.

A local pricing decision, tender outcome, or confidential concession in one market can now trigger immediate, quantifiable consequences for U.S. gross-to-net (GTN) performance, reversing foreign payers' negotiating leverage and exposing manufacturers to launch delays, margin leakage, and access friction across every referenced market.

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This article, part 2 of the series, turns from diagnosis to action. It provides a practical blueprint for the next 90 to 180 days, covering the immediate priorities companies should act on across six functional domains, a data readiness checklist to assess current maturity, and the technology capabilities required to move from fragmented, spreadsheet-driven pricing to a governed, simulation-ready operating model.

What to do now: Immediate priorities

Moving from reactive firefighting to a more resilient operating model requires focused action across six domains. Table 1 summarizes the most important near-term steps companies are taking, informed by the structural risks and practical lessons from real-world international reference pricing (IRP) and MFN experiences. The overview is intentionally two-sided:

- International pricing defenses that protect U.S. profit and loss (P&L)
- U.S. government pricing and GTN operations that convert those defenses into calculated rebates, accruals, and compliance filings

Table 1

Functional domain	Immediate action items and practical steps
Commercial pricing defenses	• Immediately require "executive-level" justification for any proposed public list price reduction globally, if within one of the MFN baskets. • Shift local net price concessions to confidential mechanisms (e.g., managed entry agreements, risk-sharing contracts, volume rebates) wherever possible. However, this likely will not prevent retrospective adjustments to the net price. • Establish and enforce mandatory global minimum price floors by therapeutic area. • Implement monthly foreign exchange (FX) impact tracking focused on markets that influence MFN reference baskets.
Launch and supply strategy	• Re-sequence upcoming launches to prioritize resilient, non-referenced, or high-income markets first; explicitly model historical launch-delay patterns in IRP-sensitive markets. • Assess from a pure economic perspective whether to voluntarily delay entry into low-price countries that serve as key anchors in the GENEROUS and GLOBE reference baskets. • Use alternative early access routes (e.g., compassionate use, named-patient programs) to generate early volume and real-world evidence without establishing an official price anchor.
Governance and compliance	• Set up automated tracking of statutory deadlines and comment periods across GENEROUS, GLOBE, and GUARD. • Require documented business-case rationales for all local pricing exceptions that approach defined risk thresholds, including consideration of country reactions and access impacts. • Maintain a centralized, audit-ready record of all MFN-related pricing decisions to support future Centers for Medicare and Medicaid Services (CMS) or U.S. Department of Health and Human Services Office of Inspector General (OIG) reviews.

Functional domain	Immediate action items and practical steps
U.S. commercial alignment	• Embed real-time international price tracking directly into U.S. pricing models and ideally GTN forecasting. • Build automated data feeds that push material global price changes to U.S. government pricing and contracting teams. • Create a cross-functional MFN rebate modeling team responsible for projecting EBITDA exposure from international pricing actions and potential voluntary MFN-type agreements.
U.S. government pricing and rebate operations	• Stand up proactive MFN exposure modeling by U.S. channel: – Medicaid (GENEROUS and statutory unit rebate amount [URA]) – Medicare Part B (GLOBE, average sales price [ASP], and inflation rebate interaction) – Medicare Part D (GUARD, Manufacturer Discount Program [MDP], benefit redesign, and inflation rebate interaction) – Commercial (contracted rebates, 340B, and downstream best price [BP] and average manufacturer price [AMP] effects) • Decide where incremental MFN rebates will be calculated: inside the revenue management or government pricing system of record or in a controlled satellite model that feeds that system. If outside, inventory whether AMP, BP, ASP, wholesale acquisition cost (WAC), unit, class-of-trade, 340B, and international benchmark inputs exist and reconcile. • Map WAC strategy (list price increases, freezes, or reductions) against MFN benchmarks, statutory Medicaid URA, BP, ASP, commercial contracts, and state price transparency reporting (SPTR) triggers. • Document the calculation methodology for new MFN and Guaranteed Net Unit Price (GNUP)-style supplemental rebates (e.g., supplemental rebate = WAC – [GNUP + URA] under GENEROUS) and the data owners for each input.
U.S. GTN and accounting	• Embed MFN rebates into GTN prospectively (forecast and accrual) and retrospectively (true-up after CMS reconciliation and restated international net prices). • Align finance, government pricing, and commercial on reserve policy, period-end close, and restatement rules when a foreign net price change or CMS invoice revises prior-period exposure. • Ensure GTN waterfalls separately identify statutory Medicaid URA, MFN incremental rebates, Medicare Parts B and D inflation rebates, commercial rebates, and 340B so leakage is visible by program.



Quick win

Within 30 days, mandate that every new international pricing or launch decision includes a one-page MFN exposure summary detailing current benchmark position, sensitivity analysis, and recommended guardrails. This single process change dramatically reduces blind-spot risk and builds the muscle for technology-enabled governance.

Data readiness checklist

Before launching the roadmap, quickly assess your current data foundation. Many organizations struggle with global pricing management implementation, not just because of the technology, but because of poor underlying data quality.

- Do you have a reasonably complete view of current list prices across all active markets?
- Do you have reasonable access to realized net prices (including confidential rebates) for key reference countries?
- Can you easily identify which of your products by U.S. channel (Medicaid, Medicare Part B, Medicare Part D, commercial, and 340B) fall under GENEROUS, GLOBE, or GUARD exposure criteria?
- Do AMP, BP, ASP, WAC, and statutory URA live in a system of record that can accept an incremental MFN or GNUP rebate type? Or would calculation sit outside revenue management, and if so, do you have the required inputs?
- Do you have reliable FX data feeds for the currencies that most influence the active MFN reference baskets?
- Is there at least one source (even if imperfect) for historical launch dates and pricing decisions?
- Can finance accrue MFN rebates in GTN prospectively and true them up retrospectively when CMS invoices or international net prices are restated?
- Do you have a current inventory of SPTR obligations (e.g., state, trigger, deadline, WAC definition) so that a U.S. list price move made for MFN reasons does not create a reporting miss?

If you answered "no" to more than two of these questions, consider running a short two- to three-week data cleanup sprint before heavily configuring the technology.

Technology: Moving from data chaos to control

Fragmented local ERPs, region-based Excel spreadsheets, and quarterly email updates are fundamentally mismatched to an environment where a small price change in one market can trigger millions of dollars in U.S. rebate exposure, and where real-world evidence shows that launch delays and strategic channel choices are common manufacturer responses. Leading companies are consolidating global pricing into a single, purpose-built platform that serves as the system of record for commercial and government pricing decisions.

A modern global pricing management and U.S. revenue management ecosystem typically delivers six core functions that manual processes cannot match at scale:

1. **Compliance with pricing policy and governance.** All relevant list and net prices are entered and maintained across all countries in which the organization sells. Any price change request will require approval in accordance with the pricing policy and governance, including any necessary business case justification and compliant documentation for traceability purposes.
2. **Automated IRP engines.** The system continuously maintains public list prices and net price data and applies the relevant reference rules across the GENEROUS, GLOBE, and GUARD baskets in real time. Proposed changes in one market are instantly modeled to assess their impact on referenced markets, including the U.S. This directly addresses the ripple effect and data comparability challenges observed in existing IRP systems.
3. **What-if simulation and impact modeling.** Before any local discount or tender bid is executed, teams can run a digital scenario that weighs the local volume opportunity against the projected U.S. rebate or list price consequences,

as well as potential launch sequencing or access impacts. This turns a complex cross-border financial and strategic question into a clear, near-instantaneous business case.

4. **Localized scenario optimization.** The platform lets regional teams explore alternative concession structures (e.g., volume-based rebates, outcomes-linked agreements, confidential mechanisms) that stay within centrally defined guardrails while still meeting local payer demands, helping preserve differential pricing flexibility that pure IRP systems often undermine.
5. **Direct integration with U.S. government pricing systems.** Clean, audited international pricing data flows automatically into the calculations for AMP, BP, ASP, and related statutory metrics. This eliminates data lag, reduces manual reconciliation, and creates a continuous audit trail for CMS submissions — critical in an environment of heightened scrutiny and potential retrospective adjustments.
6. **U.S rebate calculation and GTN.** As the global pricing management solution feeds the benchmark, the revenue management system (or a controlled satellite) calculates the incremental U.S. rebate across impacted channel(s), and finance books it in GTN and trues it up after CMS.

Global pricing management solutions and revenue management systems are purpose-built for exactly this set of requirements, bridging the historical divide between international commercial operations and U.S. statutory compliance while giving companies the agility to respond to the kinds of strategic manufacturer and country reactions observed in practice.



MFN simulation use cases

- **Confidential versus list price strategy:** Model the impact of moving concessions from public list prices to confidential net pricing mechanisms in several European reference countries.
- **Launch sequencing optimization:** Compare multiple launch sequences across 12 to 15 markets and rank them by risk-adjusted net present value (NPV) under current GENEROUS and GLOBE rules.
- **Country reaction scenarios:** Stress-test what happens to U.S. exposure if Germany or France adjusts its IRP methodology in response to increased U.S. referencing of European prices.
- **Tender response modeling:** Simulate accepting a lower net price in key reference market tenders and instantly see the projected U.S. Medicaid and Medicare rebate impact over five years.
- **U.S. channel exposure:** Size incremental Medicaid, Medicare Parts B and D, and commercial rebate impacts of a 10% net price move in a GENEROUS or GLOBE reference country.
- **WAC decision:** Compare freeze versus reduce versus increase WAC and show AMP, BP, ASP, statutory URA, MFN supplemental rebate, commercial price protection, and SPTR filing consequences.
- **Calculation architecture:** Test whether the revenue management system can produce the MFN rebate versus a satellite model, and flag missing data (e.g., units, 340B, international nets, FX).
- **GTN accrual versus true-up:** Model the P&L difference between accruing MFN exposure now versus recognizing it only after CMS reconciliation.

The 90- to 180-day execution roadmap

Transforming pricing capabilities in this environment cannot wait for a multiyear systems program. Companies need to achieve stability quickly and then layer on automation. This phased approach has proven effective in practice and incorporates lessons from real-world IRP friction and manufacturer responses.

Days 0 to 30: Diagnose and map

Objective: Establish a clear baseline of exposure and identify immediate vulnerabilities, including markets where launch delays or channel shifts have historically occurred.

1. Map every commercial asset against the GENEROUS, GLOBE, and GUARD exposure criteria (e.g., therapeutic class, spend thresholds, launch status) and flag markets with known IRP sensitivity or history of delayed launches.
2. Pull current public list prices and confidential net prices across all active markets into a secure, temporary registry, noting data gaps that mirror real-world transparency challenges.
3. Assess current data architecture (e.g., local ERPs, spreadsheets, handoffs) to define the integration scope for a global pricing management solution, with priority on high-risk reference markets.
4. Assess in parallel whether the U.S. revenue management system already contains the AMP, BP, ASP, WAC, unit, and 340B data needed to calculate MFN rebates in-system, or whether a satellite model is required.

Deliverables:

- MFN exposure heatmap
- Prioritized list of highest risk products
- U.S. channel exposure snapshot
- Revenue management system versus satellite data-gap list

Success metrics:

Exposure register completed and validated by the global pricing committee.

Key pitfall to avoid:

Trying to achieve perfect data completeness in the first 30 days. Focus on "good enough" data for the top 10 to 15 products by U.S. exposure.

Days 30 to 90: Stabilize and govern

Objective: Stop uncontrolled leakage and establish basic guardrails, informed by observed manufacturer tactics such as channel prioritization.

1. Formally charter the global pricing committee and regional committee.
2. Codify the green, amber, and red escalation rules in corporate policy, explicitly including launch sequencing and country-reaction considerations.
3. Entrust U.S. government pricing, GTN and finance, and compliance (SPTR) to the committee so WAC and rebate-methodology decisions are not made only by international pricing.
4. Issue an immediate global freeze on uncoordinated public list price reductions and introduce interim manual-simulation checklists while the technology is being configured.
5. Stand up a monthly FX monitoring protocol focused on the currencies and markets that most influence the active MFN reference baskets, plus a watch list for emerging country policy shifts.

Deliverables:

- Approved global pricing policy
- WAC and SPTR rule
- GTN accrual policy
- First version of the MFN decision log

Success metrics:

100% of new pricing decisions use the MFN exposure summary template, and zero unapproved list price reductions occur in reference markets.

Key pitfall to avoid:

Over-engineering governance processes too early. Keep rules simple and tighten them iteratively based on real decisions.

Days 90 to 180: Transform and automate

Objective: Replace manual processes with enterprise-grade automation and full compliance integration.

1. Go live with the global pricing management solution, retire localized pricing spreadsheets, and enable rapid what-if modeling of launch sequencing and channel strategies.
2. Connect global pricing management outputs to the U.S. government pricing and revenue management stack and to GTN accruals, so simulated international moves are booked as U.S. exposure, not just a slide.
3. Train global, regional, and local users on the what-if simulation and localized scenario optimization modules, with emphasis on modeling potential country countermeasures and access impacts.
4. Establish secure, automated data pipelines from the global platform into U.S. government pricing compliance systems, with full audit trails for CMS and the ability to simulate interactions with all MFN-type agreements.

Deliverables:

- Live global pricing management environment with simulation capability for top products
- Documented integration with U.S. statutory pricing for U.S. revenue management calculations and reporting

Success metrics:

Simulation is used in at least 80% of major pricing and launch decisions, and manual data reconciliation time decreases by at least 50%.

Key pitfall to avoid:

Underinvesting in change management and user training. Technology without adoption delivers limited value.



Investment and ROI

Typically, an investment in a global pricing management solution (software and implementation) for a mid- to large pharmaceutical manufacturer is recouped within 12 to 18 months through avoided price erosion, optimized launch sequencing, reduced manual effort, and, critically under MFN, prevention of multi-million-dollar rebate leakage. The cost of inaction is far higher.

Conclusion: Technology as a competitive advantage

This phased 90- to 180-day roadmap is deliberately pragmatic. It recognizes that companies cannot wait for a multiyear enterprise program while GENEROUS moves through pre-implementation (with participation agreements finalized as of July 2026), GLOBE and GUARD advance toward mandatory application for qualifying high-spend products, and voluntary MFN commitments continue to reshape commercial strategy. The objective is rapid stabilization, followed by automation: First, stop uncontrolled leakage, then replace manual processes with enterprise-grade capabilities.

The current state of technology across the industry remains predominantly basic to intermediate. Many organizations still rely on local ERPs, regional spreadsheets, and periodic manual handoffs. Data on realized net prices, reference basket positioning, and cross-market exposure is often incomplete or lagged. Scenario modeling, when performed, tends to be ad hoc and too slow for timely decisions. Governance is frequently reactive rather than embedded, creating margin leakage and compliance risk.

Leading companies are consolidating global pricing into purpose-built **global pricing management** and **revenue management** platforms that directly address the gaps exposed by real-world MFN dynamics and IRP. These platforms deliver five capabilities that manual approaches cannot match at scale:

- Documented and traceable compliance to any list or net price change requests, including business case justification and approval trails, to ensure price guardrails are being maintained to avoid revenue leakage
- Automated IRP engines that maintain list and net price data across the GENEROUS, GLOBE, and GUARD baskets in real time and instantly model the U.S. impact of any proposed change across all U.S. channels
- Advanced what-if simulation that converts complex cross-border questions ("What if we approve this tender price or launch sequence?") into clear, near-instantaneous business cases showing U.S. rebate exposure, rebate architecture, GTN, overall NPV, and access implications
- Localized scenario optimization that lets regional teams explore alternative concession structures, such as confidential mechanisms and volume-based or outcomes-linked agreements, while staying inside centrally defined guardrails and preserving the differential pricing flexibility that pure IRP systems often undermine
- Direct, audited integration with U.S. government pricing systems (AMP, BP, ASP, and rebate engines), eliminating data lag and creating continuous compliance trails

These are not generic reporting tools. They are decision-support systems purpose-built for an environment in which a single price movement in a reference market can trigger millions in U.S. exposure, and manufacturers respond with launch delays, channel shifts, and more aggressive use of confidential structures.

The investment case is straightforward. Typically, the investment in a global pricing management solution for a mid- to large pharma manufacturer is recouped within 12 to 18 months through avoided price erosion, optimized launch sequencing, reduced manual effort, and, most importantly, under MFN, prevention of multi-million-dollar rebate leakage. The cost of continued reliance on fragmented processes is far higher, as evidenced by the launch delays, margin compression, and access friction already observed.

This article has translated the MFN mechanics and risks identified in part one of the Global Pricing Under Pressure series into an actionable roadmap and the specific technology capabilities required. Part three will complete the picture by detailing the governance model and organizational design that turns these technology capabilities from a system of record into a true, institutionally embedded decision-support engine, moving pricing authority from isolated local decisions to a coordinated global-regional-local structure.

The mechanics are clear. The risks are material and already manifesting. The technology exists and is proven in analogous IRP environments. What remains is disciplined, phased execution. Companies that move now, while the models are stabilizing, will secure defensive protection and competitive optionality. Those that continue with reactive, manual approaches will face the same cycle of leakage, delays, and access friction that has characterized every prior wave of IRP.

The window to build resilience is open but narrowing. Disciplined action now converts regulatory pressure into structured advantage.

Call to action

1. Complete the 30-day MFN exposure diagnostic on your top portfolio assets and map them against GENEROUS, GLOBE, and GUARD criteria.
2. Decide the MFN rebate calculation architecture (in a revenue management system versus controlled satellite) and close any AMP, BP, ASP, WAC, and utilization data gaps.
3. Charter the global pricing committee (or equivalent) and codify green, amber, and red escalation rules within 60 days, ensuring U.S. and international pricing involvement.
4. Stand up a product-level U.S. exposure model covering Medicaid, Medicare Parts B and D, and commercial, and link it to GTN accruals and retrospective true-ups.
5. Attach SPTR and WAC-governance checks to every MFN-related U.S. list price recommendation before it is executed.
6. Stand up the interim monthly FX and reference-basket monitoring protocol immediately.
7. Define the target global pricing management use cases (simulation priorities, integration scope with U.S. government pricing) and begin platform evaluation or configuration within the 90-day window.
8. Align global pricing, U.S. government pricing, market access, and finance on a single shared roadmap and success metrics before day 90.

Ready to trade spreadsheet chaos for simulation-driven control?

Talk with the Model N team to assess your data readiness and pinpoint the global pricing management capabilities you need to move through the 90- to 180-day roadmap.

About Marbls

Marbls partners with pharmaceutical and medical device and diagnostic manufacturers to provide practical, innovative services that address complex pricing, contracting and commercial excellence needs — driving the path of critical drugs, devices, and diagnostics to market. Learn more at ***marblsgroup.com*** *or reach out to* ***themarblsteam@marblsgroup.com****.*

About Model N

For more than 25 years, Model N has been the leader in end-to-end commercialization, revenue optimization, and compliance for pharmaceutical and medtech innovators. Our intelligent platform, purpose-built solutions, and advanced analytics and AI automation are trusted by more than 110 of the world's leading companies. For more information, visit ***modeln.com****.*