GIBSON DUNN · LIFE SCIENCES WEBCAST

PHARMA MFN REFORMS

Deal Structuring in a Reference-Pricing World

How most-favored-nation pricing commitments reach into licenses, earnouts, and contingent value rights — and how to draft for them.

Ryan Murr · Margaux Hall · Karen Spindler · Branden Berns

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TODAY'S PANEL

Speakers and Roadmap

Ryan Murr
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Partner, Washington, D.C. FDA & Health Care. Drug pricing, market access, and reimbursement.

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Partner, San Francisco. Life Sciences. Licensing, collaborations, and IP transactions.

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Partner, San Francisco. Life Sciences. Mergers & Acquisitions.

I	Framing — why MFN is now a deal issue	Ryan Murr	5 min
II	The regulatory landscape — what MFN actually requires	Margaux Hall	15–20 min
III	Licensing in an MFN world	Karen Spindler, with Margaux Hall	15 min
IV	M&A earnouts and CVRs	Branden Berns, with Ryan Murr	15 min
V	Moderated discussion and Q&A	All panelists	5–10 min

Why MFN Is Now a Deal Issue

Reference pricing creates a feedback loop: a price set anywhere in the basket becomes an input to the U.S. price. Every contract that touches ex-U.S. commercialization — a license, an earnout, a CVR — can now carry U.S. pricing exposure.

EX-U.S. PRICE EVENT

A launch, discount, or reimbursement cut in a reference country

Often set by a licensee, distributor, or local authority — not the U.S. rights holder

→

MFN BENCHMARK

The lowest basket-country price sets the U.S. target or rebate

Via manufacturer agreements, GENEROUS, and the proposed GLOBE / GUARD models

→

U.S. DEAL ECONOMICS

Royalties, earnout thresholds, and CVR milestones absorb the cut

Sales-based payments measured on "Net Sales" compress with every mandated rebate

> **The through-line of the hour:** what counts in the reference price — and what counts as "Net Sales" — is the same drafting problem in licenses, earnouts, and CVRs. Solve it once, consistently, across the deal stack.

THE REGULATORY LANDSCAPE

What MFN actually requires — the executive orders, the manufacturer agreements, the three CMS models, and the trade-based enforcement risk that accompanies them.

01

Fourteen Months from Order

An evolving policy priority with multiple prongs: an executive order stating the principle, bilateral, bespoke manufacturer agreements with MFN-related provisions, CMS models invoking CMMI authority to “test” it, and tariffs to enforce it.

May 12, 2025
EO 14297: Directing HHS to publish MFN pricing benchmarked to comparably developed nations; DTC provisions

Jul 31, 2025
Letters to 17 manufacturer CEOs demanding MFN commitments

Sep 30, 2025
Pfizer agreement — the framework: Medicaid MFN, MFN launch pricing, tariff relief

Nov 6, 2025
Lilly and Novo Nordisk agreements announced; DTC pricing via TrumpRx

Dec 19, 2025
CMS proposes GLOBE (Part B) and GUARD (Part D) MFN Medicare rebate “models”

Jan 2026
GENEROUS Medicaid “model” launches – application deadline later extended; 16 manufacturers have announced MFN deals

Feb 5, 2026
TrumpRx.gov DTC platform goes live — 43 drugs from five manufacturers at launch

Apr 2, 2026
Section 232 proclamation: tariffs up to 100%, relief tied to MFN agreements

Manufacturer agreement terms are confidential; publicly announced framework terms only. Sources: EO 14297 (90 Fed. Reg. 20819); CMS Innovation Center; White House proclamation of April 2, 2026.

The Three CMS "Models"

	GENEROUS GENErating cost Reductions fOr US Medicaid	GLOBE Global Benchmark for Efficient Drug Pricing	GUARD Guarding U.S. Medicare Against Rising Drug Costs
PROGRAM	Medicaid — supplemental rebates on selected drugs	Medicare Part B — high-cost single-source drugs and biologics in 7 therapeutic classes	Medicare Part D — single-source / sole-source drugs in 17 therapeutic classes
STATUS	**Live.** State and manufacturer opt-in. Launched January 2026	**Proposed** Dec. 19, 2025. Mandatory participation if finalized. Proposed start Oct. 1, 2026	**Proposed** Dec. 19, 2025. Mandatory if finalized. Proposed start Jan. 1, 2027
MECHANISM	Supplemental rebate bringing the Medicaid net price to the international benchmark	MFN-based rebate in lieu of the Part B inflation rebate for covered drugs; 125% penalty on unpaid rebates	MFN-based rebate in lieu of Part D inflation rebate; same 125% penalty structure
REFERENCE BASKET	8 countries — Canada, Denmark, France, Germany, Italy, Japan, Switzerland, U.K.	19 OECD countries — GDP-per-capita at least 60% of the U.S. and GDP of at least $400 billion	Same 19-country basket and benchmark methodology as GLOBE
KEY EXCLUSIONS	Participation is elective; selected-drug lists negotiated state by state	Drugs under $100M in Part B FFS spend; 340B, IRA-negotiated drugs	Drugs under $69 million annual spend, 340B, IRA-negotiated drugs

> **Unresolved:** several MFN-agreement signatories have stated their deals exempt them from GLOBE and GUARD. CMS has not confirmed the exemption — or whether it would cover the signer's full portfolio, including future launches.

How the Benchmark Is Built — and Why Deal Lawyers Care

As proposed, GLOBE and GUARD set the rebate from an international benchmark — a **default or manufacturer-elected** method, adjusted for purchasing-power parity.

METHOD I · DEFAULT

Lowest observed price in the basket

The lowest country-level average price across the 19 reference countries, drawn from commercial data sources — **IQVIA MIDAS, GlobalData POLI, Eversana NAVLIN** — set at model start and, as proposed, held constant.

Threshold adjustment: 102%. Often reflects list or invoice prices, not confidential nets.

METHOD II · MANUFACTURER OPTION

Volume-weighted average net price

The manufacturer may elect to submit its own net pricing data across the basket; if accepted, CMS would use the volume-weighted average net price, updatable each performance year.

Threshold adjustment: 105%. Rewards keeping true nets confidential but documented.

ENFORCEMENT

125%

Civil monetary penalty on the unpaid rebate amount for manufacturers that fail to pay timely

DEAL RELEVANCE

The benchmark is computed from **third-party databases** — a licensee's list price in one basket country is visible to CMS and can set the U.S. benchmark for the whole franchise.

There is no need for a relationship between the U.S. and the ex-U.S. manufacturer.

Basket: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, United Kingdom.

Trade-Based Enforcement: The April 2026 Proclamation

Section 232 tariffs on patented pharmaceuticals and ingredients, with relief expressly tied to MFN pricing agreements and domestic-production commitments. Tariff exposure now tracks **deal status**, not geography.

100%	Default rate on patented (Orange / Purple Book) pharmaceuticals and APIs — no onshoring plan, no MFN agreement	Generics, biosimilars, and orphan drugs exempt for now
10–15%	Country-agreement rates — 15% for the EU, Japan, Korea, Switzerland, Liechtenstein; 10% for the U.K., reducible to zero under the December 2025 pricing framework	Conditioned on manufacturers entering the negotiated MFN and tariff agreements
~20%	Transitional rate for companies with a Commerce-approved onshoring plan, pending completion	Periodic progress reporting against onshoring milestones required
0%	**Onshoring plan + signed MFN pricing agreement with HHS** — zero tariff until January 20, 2029. Thirteen company-specific agreements (Dec. 2025 – Mar. 2026) ratified by the proclamation — a subset of the sixteen-plus announced to date	"Likely soon to have" an agreement — including agreements in principle — qualifies per the proclamation; guidance pending

Effective July 31, 2026 for the 17 large companies in Annex III

Effective September 29, 2026 for all other companies

For deal drafting: a tariff is a COGS event — not a Net Sales deduction

What Remains Fluid

Legal authority

- Whether a **mandatory, nationwide** GLOBE / GUARD exceeds CMMI's statutory authority to "test" models
- APA challenges to benchmark methodology and data sources; likely Constitutional challenges
- Section 232's reach when tariff relief is conditioned on **domestic price** commitments

Political durability

- Congressional scrutiny of whether confidential deals deliver **verifiable savings**
- Agreement terms undisclosed — independent verification impossible
- Deal architecture can be extended, renegotiated, or abandoned by either side

Open design questions

- **Which prices count** — list, invoice, or confidential net
- Launch pricing for new drugs vs. in-line repricing
- Scope of any GLOBE / GUARD exemption for MFN-agreement signatories
- Final basket, thresholds, and effective dates

> **Drafting consequence:** allocate MFN risk by **category and effect** — "any government-mandated or -benchmarked price reduction, or any successor or similar program" — so the allocation survives an injunction, a repeal, or a replacement model.

LICENSING IN AN MFN WORLD

Out-licensing ex-U.S. rights now creates U.S. pricing exposure. Pricing controls, emerging workarounds, and what to do about legacy agreements.

02

The Core Tension: Whoever Prices the Basket Prices the U.S.

The territorial license separates **who sets the ex-U.S. price** from **who bears the U.S. consequence**. MFN reconnects them — without renegotiating the contract.

THE LICENSOR (U.S. RIGHTS)

- Keeps the U.S. P&L — now benchmarked to the lowest basket price
- May have signed an MFN agreement covering **launch pricing** for new products
- Holds no pricing authority in the licensed territory

⇄ MIS-ALIGNED

THE LICENSEE (EX-U.S. RIGHTS)

- Sets — or concedes to reimbursement authorities — prices in basket countries
- Optimizes for local access, volume, and its own margin
- Bears none of the licensor's U.S. price consequence

WHY ROYALTIES DON'T SOLVE IT

A royalty on the licensee's local sales is trivial next to the U.S. franchise. A price that costs the licensee little can cost the licensor its U.S. margin.

AND IT CUTS BOTH WAYS

A licensee taking U.S. rights should ask what ex-U.S. pricing the licensor — or its other licensees — can commit elsewhere that drags the licensee's U.S. price.

Pricing Controls in the License Agreement

01 Consultation and notice rights

Advance notice of list price, launch price, and material reimbursement concessions in defined reference countries. Weak, but preserves visibility and a record.

02 Pricing approval rights

Licensor consent to initial price and price reductions in basket countries — the strongest control, and the most heavily negotiated and legally constrained.

03 Floor prices

A defined minimum net (or list) price per reference country, often expressed as a percentage of the U.S. price — with agreed consequences, not just a covenant.

04 Launch sequencing

U.S. launch first; reference-country launches ordered so early, price-controlled markets do not set the benchmark before the U.S. price is established.

05 Right to withhold launch

Licensor consent required to launch — or to accept reimbursement — in named basket countries where the achievable price would damage the U.S. benchmark.

06 Data and audit rights

Net-price reporting per reference country, in the form CMS accepts for Method II submissions — the licensor cannot document what it cannot see.

The legal limit: antitrust and competition law — U.S. resale-price rules and their stricter ex-U.S. counterparts — plus local reimbursement law constrain direct control over a licensee's prices. Shape **territory, sequencing, and consequences** rather than dictating the number.

Emerging Workarounds

STRUCTURE	WHAT IT DOES	WATCH POINT
Reference-basket pricing covenants	Pricing obligations defined against the contract's own basket — floors, notice, and consent keyed to the countries that actually set the U.S. benchmark	Define the basket by category and effect ("any U.S. reference-pricing program"), not by citation to a rule that may change
Confidential net pricing	Rebate-heavy architectures keep list and invoice prices high while the real price moves through confidential rebates — blunting benchmarks built from list-price data	Method II invites disclosure of true nets; a future model could mandate net-price data. Local transparency laws are tightening
Territory carve-outs	Exclude the most damaging basket countries from the licensed territory entirely — no launch, no reference price	Foregoes revenue and may raise access and reputational issues; parallel-trade rules limit the seal in the EU
MFN-triggered royalty adjustments	Royalty rates or milestone economics re-set automatically when a defined reference-price event compresses the licensor's U.S. net price	Requires a measurable trigger and clean data; draft the computation and dispute mechanics up front
Termination and clawback rights	Territory-by-territory termination, or recapture of rights, tied to sustained reference — price erosion or breach of pricing covenants	The remedy must be worth exercising — pair with transition assistance and data-transfer obligations

Legacy Agreements, Diligence, and the Antitrust Boundary

Agreements silent on MFN

Map the exposure: every ex-U.S. license, distribution, and supply arrangement, overlaid on the 19-country basket — who sets price, where, with what constraints

Read the general clauses: commercially-reasonable-efforts, cooperation, and compliance-with-law provisions do unexpected work when a pricing regime arrives mid-term — and a Net Sales definition with generic GAAP-deduction language may already absorb MFN rebates by default

Renegotiation leverage: MFN protections are traded into amendments — alongside milestone relief, field expansions, or term extensions — not negotiated in the abstract

New deals: treat the pricing covenant, the basket definition, and the adjustment mechanics as core commercial terms, not boilerplate

The antitrust boundary (U.S. and ex-U.S.)

Direct control of a licensee's resale prices raises **RPM and price-fixing** exposure — analysis differs sharply between the U.S. and the EU and by member state

Information exchange on pricing between actual or potential competitors requires careful structuring — clean teams, aggregation, counsel oversight

Withholding launch or supply in a basket country can draw **abuse-of-dominance and access** scrutiny ex-U.S.

Document the **independent business rationale** for pricing-related terms contemporaneously — the file will be read later

Bridge to Section IV: the same feedback loop that erodes a royalty erodes a sales milestone — but in M&A the instrument is often public, trustee-administered, and litigated. Same drafting problem, higher stakes.

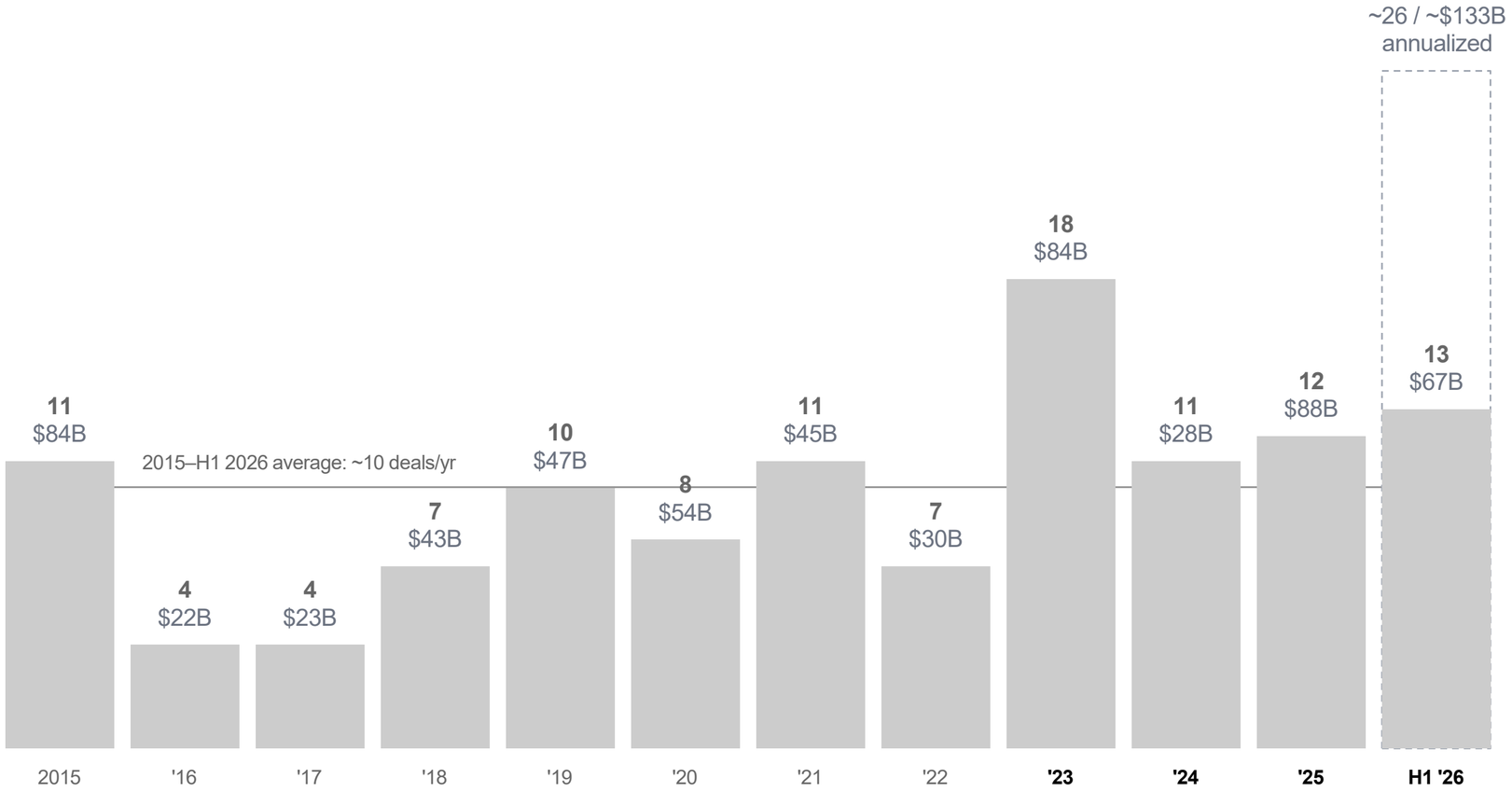
M&A EARNOUTS AND CVRS

Net Sales definitions under pressure, milestone mechanics, efforts covenants, and who bears the risk of models that are proposed but not yet final.

03

Biopharma M&A Deal Activity by Year

Announced $1–25 billion public-target biopharma acquisitions. Volume has re-accelerated since 2023 — and a growing share of these deals now carries a CVR.



Deal count (bars) with aggregate upfront equity value ($B); dashed bar shows the 2026 annualized run-rate. Source: Gibson Dunn Biopharma M&A Survey (1H 2026) — $1–25B public-target biopharma acquisitions; 2024 value approximate.

13 / $66.6B

deals and upfront value in H1 2026 — a ~26-deal, ~$133B annualized pace

$200B+

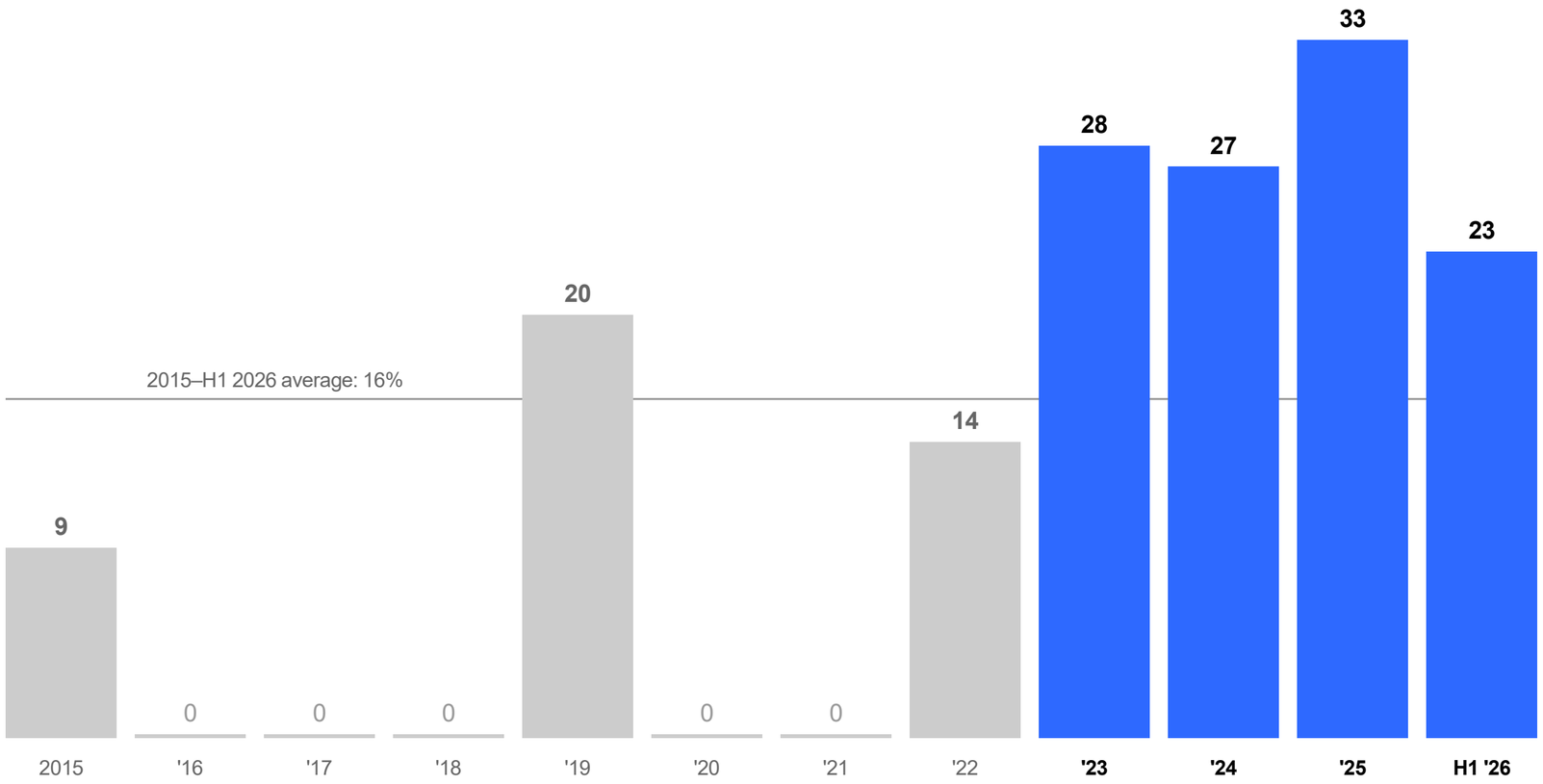
of large-pharma revenue faces loss of exclusivity by 2030, driving buy-side demand

Volume up, CVRs up

As the deal pace accelerated from 2023, CVR usage rose with it — from under 10% of deals before 2019 to 23–33% every year since. The next slide tracks that shift.

The Rise of the CVR — and of the Sales Milestone

Share of $1–25 billion public-target biopharma acquisitions including a CVR, by year. In the surveyed deals, net-sales milestones first appear in 2025–2026 — exactly as MFN began compressing the metric they measure.



% of deals with a CVR. Source: Gibson Dunn CVR Drafting Guide (July 2026) — all CVR agreements, $1–25B public-target biopharma acquisitions, 2015–H1 2026.

19 of **116**

deals in the segment included a CVR, 2015–H1 2026

23–33%

of deals every year since 2023 — never above 9% before 2019

5 deals

Net-sales milestones — all signed 2025–2026. The newest milestone type carries the most measurement risk, and by default its holders bear the pricing-policy risk.

"Net Sales" Under Pressure: The Definitional Battleground

Whether MFN and IRA price cuts **deduct from** Net Sales or are **added back** is the single most consequential choice in a sales-based milestone. In the 2025–26 net-sales CVRs to date, government rebates and IRA price cuts deduct — the holder bears the policy risk by default.

POLICY ITEM	BUYER-FAVORABLE — DEDUCT (LOWER NET SALES)	SELLER / HOLDER-FAVORABLE — ADD BACK
IRA maximum fair price	Count covered units at the negotiated (reduced) price	Measure covered units at a pre-MFP reference price, or add back the MFP delta
MFN / government-benchmarked cuts	Deduct — the lower realized price flows through to the milestone	Add back government-mandated reductions; gross up to a defined benchmark price
Mandatory statutory rebates (incl. GENEROUS / GLOBE / GUARD)	Deduct as a Net Sales reduction, consistent with GAAP and historical methodology	Exclude statutory / mandatory rebates from deductions — distinguish them from negotiated commercial rebates
Section 232 tariffs	N/A — a cost-of-goods item, not a revenue deduction	N/A — relevant only if a profit or margin metric is used. **Net-sales metrics avoid importing tariff cost risk**

> **Do not inherit the allocation by silence.** A "deductions consistent with GAAP" default quietly assigns every future pricing program to the holder. Address each vector expressly — and define triggers by category and effect, including "any successor or similar program."

Earnout Mechanics in a Reference-Pricing World

Calibration

Outstanding milestones were priced off **pre-MFN forecasts**. A threshold set on 2023 pricing assumptions may now be structurally unreachable.

Worldwide, cumulative measurement over rolling periods; fixed FX conventions

Reference-price counting for units subject to MFN / MFP pricing

Realistic thresholds stress-tested against the models' rebate math

Adjustment

Should thresholds **re-set** when a pricing regime changes mid-earnout?

Automatic adjusters keyed to defined regulatory events beat renegotiation — if the trigger is measurable

Alternative: measurement hold-harmless — lawful price cuts do not reduce Net Sales below a benchmark

Independent-accountant expert determination for the computation, final absent manifest error

The efforts question

Does **signing an MFN agreement** that cuts the product's price breach a commercialization-efforts covenant — or is it protected?

Turns on the chosen benchmark: objective comparable-company vs. buyer discretion

"Compliance with law is not a breach" protects mandates — an **unmandated** deal is harder to shelter without the express carve-out below

Courts enforce the words; the implied covenant will not reallocate a foreseeable risk

> **The pairing that works:** the buyer gets an express "compliance with any government price program is not a breach" carve-out; the seller gets a Net Sales hold-harmless so the resulting price cut cannot silently defeat the milestone. Freedom to comply — neutralized measurement.

CVR-Specific Issues: Public Instruments, Public Fights

Enforcement plumbing decides cases

A ~$6.4 billion CVR claim was dismissed for lack of standing — the trustee had been appointed by beneficial holders while the registered holder (Cede & Co.) held 99%+ of the CVRs. For DTC-held CVRs, **give beneficial holders express rights** to direct and replace the trustee and to sue in their own name; set acting-holder thresholds deliberately (recent deals: 32.5–50%).

Pricing-regime carve-outs

Define MFN triggers by **category and effect** — "any government-mandated or -benchmarked price reduction, including under EO 14297 or any successor or similar program" — so the allocation survives an injunction, repeal, or replacement. A citation to a specific rule is a bet on that rule's survival.

Reporting and audit

Most CVRs grant only books-and-records access. For a net-sales milestone in an MFN world, holders need **periodic milestone-status reporting** and audit rights over the gross-to-net waterfall — courts credit contemporaneous documentation over post-hoc rationales.

Disclosure considerations

Projections supporting CVR value in the proxy or 14D-9 should carry **MFN sensitivity**; efforts-covenant descriptions must match what the buyer actually intends; and a buyer's own MFN agreement is now a fact bearing on its milestone-related disclosure.

Enforcement example: UMB Bank v. Bristol-Myers Squibb (S.D.N.Y.) — standing dismissal Sept. 2024; motion to dismiss the refiled action denied Dec. 2025. See the Gibson Dunn CVR Drafting Guide (July 2026) for the full case synthesis.

Allocating MFN Risk in the Deal

Four places to put a risk that is real but unquantified — models proposed, terms confidential, litigation pending.

01 Purchase price

Price the exposure into the upfront and the milestone sizes. Clean, but requires modeling GLOBE / GUARD rebate math on the target's portfolio — with confidence intervals nobody yet has.

02 MFN reps and covenants

Reps on MFN-agreement status, reference-country pricing posture, and model eligibility; interim covenants restricting new or amended MFN commitments between signing and closing without consent.

03 Milestone architecture

Front-load policy-insulated milestones — regulatory approval, first commercial sale — and treat sales milestones as upside with worldwide, cumulative, realistically-set thresholds.

04 Measurement neutralization

The Section IV toolkit: category-and-effect triggers, express Net Sales treatment per policy vector, reference-price counting, hold-harmless benchmarks, and expert determination of the computation.

> **A negotiable default for proposed-but-not-final models:** the party that controls the response to the regime — whether to sign an MFN deal, how to price the basket — bears its measurement consequence. Control and consequence in the same hands.

CLOSE — MARGAUX HALL

What Could Change Before Year-End

RELATIVELY SETTLED

Sixteen-plus manufacturer MFN agreements announced and being performed — terms confidential

GENEROUS live in Medicaid; state and manufacturer participation underway

Section 232 tariffs take effect — July 31, 2026 (Annex III companies) and September 29, 2026 (all others)

TrumpRx operating and expanding as new agreements are signed

GENUINELY MOVING

GLOBE / GUARD final rules — basket, thresholds, exemptions, and the proposed Oct. 1, 2026 / Jan. 1, 2027 starts could all shift

Litigation — CMMI authority and APA challenges could stay or reshape the mandatory models

The exemption question — whether MFN signatories (and their future launches) sit outside GLOBE / GUARD

Congress — scrutiny of confidential deals could produce codification, oversight, or rollback

> **Draft for the architecture, not the rule:** category-based triggers, hold-harmless measurement, and express allocations hold up whether any particular model is finalized, enjoined, or replaced.

DISCUSSION & Q&A

Q1 Is anyone seeing MFN provisions actually negotiated in current term sheets — or is this still a diligence-memo issue?

Q2 Are MFN provisions becoming an impediment to ex-U.S. deals — and what does that do to ex-U.S. asset values?

Q3 With biopharma M&A accelerating, how do you expect CVRs to evolve to address the MFN uncertainties?

THANK YOU

Questions and Follow-Up

The Gibson Dunn CVR Drafting Guide (July 2026) — market data, model pro-buyer and pro-seller clauses, and the litigation synthesis referenced today — is available from any member of the panel.

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