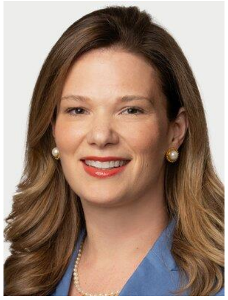
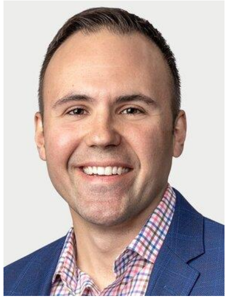
Portfolio Media. Inc. | 230 Park Avenue, 7th Floor | New York, NY 10169 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

How 'Most Favored Nation' Regime Affects Biopharma Deals

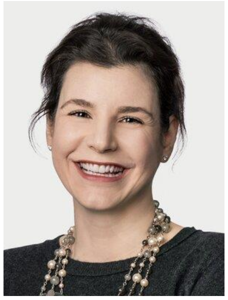
By **Margaux Hall, Branden Berns and Karen Spindler** (August 25, 2026, 3:04 PM EDT)



Margaux Hall



Branden Berns



Karen Spindler

Life sciences dealmaking is running at a record pace — straight into a pricing regime that is still being written.

According to Gibson Dunn's July biopharma M&A survey, the first half of 2026 saw 13 announced acquisitions of public biopharma targets ranging from $1 billion to $25 billion, roughly $66.6 billion in upfront value — an annualized pace exceeding any year in the survey's history.

Deal structures are shifting too: Per the firm's July 2026 contingent value rights study, CVRs appeared in under 10% of these deals before 2019, but in 23% to 33% every year since 2023 — and net-sales milestones are brand new, appearing in five deals, all signed in 2025 and 2026. The market adopted its most pricing-policy-exposed milestone structure just as U.S. pricing policy began compressing the metric it measures.

The collision is here: Section 232 tariffs of up to 100% took effect July 31, with relief expressly conditioned on most-favored-nation pricing agreements, and the proposed Global Benchmark for Efficient Drug Pricing Medicare demonstration is scheduled to begin on Oct. 1.

This article describes the current state-of-play with MFN and key deal drafting considerations.

MFN, a clear policy priority of the Trump administration, has advanced to date without legislation. Over the past 15 months since the policy was first announced through an executive order, MFN commitments have taken shape through confidential agreements between the administration and individual manufacturers, as well as ongoing or proposed Center for Medicare and Medicaid Innovation demonstration programs, including the proposed Medicare demonstration programs GLOBE and Guarding U.S. Medicare Against Rising Drug Costs.

If finalized as proposed, those two programs would replace the Inflation Reduction Act's inflation-based Medicare rebate with a new rebate benchmarked to MFN pricing across a basket of 19 countries.

These proposals are not final, and their final terms could change; if finalized, the rules are likely to draw litigation. Nonetheless, the prudent posture for dealmakers is to treat the MFN regime as durable in concept, but unsettled in detail.

Dealmakers need to carefully anticipate the implications of any MFN benchmark pricing regime as they navigate deals to help support a transaction's ultimate success. This is because once a manufacturer's U.S. price is benchmarked to the lowest — or a lower — price in a basket of developed countries, whoever sets, or fails to control, a price in one of those countries is touching the U.S. manufacturer's economics.

Because royalties, earnout payments and contingent value rights milestones are typically tied to net sales, a price cut abroad can quietly compress the value of a U.S. transaction.

Under GLOBE and GUARD, as proposed, two features of the proposed benchmark run counter to intuition and merit close consideration for deal purposes.

First, the benchmark is proposed to be presumptively built from commercial, publicly available pricing databases — with no compelled reporting from manufacturers based on their own books — taking the lowest country-level average price in the basket and fixing it for the duration of the demonstration.

Second, drugs would be matched by drug, based on product characteristics — e.g., active ingredient, route of administration, dosage form and strength.

The agency has made clear that it is not concerned with whether the same manufacturer controls pricing abroad. Even a completely separate, ex-U.S. manufacturer can influence U.S. economics with its independent pricing decisions. The consequence is significant: A licensee's published price in even a small market can set the U.S. benchmark for an entire franchise.

Further, there is no need for a corporate relationship between the foreign seller and the U.S. rights holder. This creates implicit incentives to robustly protect from disclosure net-pricing architecture, keeping list prices higher while moving real concessions into rebates. It further suggests that indicia of corporate ownership or control bear no relevance in an MFN world. Any deal that outlicenses rights can be material to the U.S. market.

For deals undertaken today, the most immediate risk lies in agreements signed before the MFN policy pronouncements in President Donald Trump's second term, as the current rules contain no grandfathering exception for existing arrangements.

Ex-U.S. licenses executed before May 2025 — silent on MFN — could carry latent U.S. pricing consequences. A key diligence exercise on any affected asset is therefore a careful mapping of every ex-U.S. license, distribution and supply agreement against relevant basket countries, asking about pricing dynamics and rights in each.

For new split-geography deals, the tension is structural. The licensor retains the U.S. profit and loss but hands price-setting in the basket countries to a licensee that bears none of the U.S. consequence, and whose incentives run toward local access and volume.

Counsel are deploying a range of control levers: consultation and approval rights; floor prices, which bind the published price that feeds the benchmark while the concessions that actually secure access migrate into confidential rebates; mandated launch sequencing so the U.S. prices first; and, at the extreme, rights to withhold launch in a market expected to set a damaging reference price.

Each lever retained by a licensor is only as strong as the information rights behind it — pricing notification, reporting and audit — and each is bounded by U.S. and ex-U.S. competition law constraining a licensor's ability to dictate downstream price, with the prohibitions on minimum resale price maintenance and, in the EU, on restricting passive sales and parallel trade posing the sharpest limits on territory- and launch-based solutions.

The prevailing answer seems to be to shape territory and sequencing rather than to dictate a number and, where control is genuinely unavailable, to price the risk instead — for example, royalty and milestone adjusters, make-whole mechanics, or reversion rights triggered if an ex-U.S. price falls below an agreed reference level.

However, none of these structures has yet been tested in a dispute, and, for now, they are adding a negotiating axis and time to cross-border licensing.

Tariffs — being imposed on various branded drugs — also influence the deal-making landscape. In considering the impact of tariffs, it is worth noting that a tariff is a cost-of-goods event rather than a net-sales deduction — so sales-based milestones quarantine tariff exposure in a way profit-based metrics do not.

In public company mergers and acquisitions, CVRs — effectively an earnout for target shareholders — have only very recently begun to utilize net-sales milestones, a milestone formulation that ironically started gaining traction just as these pricing programs arrived.

Every sales-based milestone turns on a single question: Does a government-driven price cut deduct from net sales, or is it added back for purposes of measuring the milestone? In each of the net-sales-milestone deals done to date, such cuts deduct — meaning CVR holders bear the policy risk by default and the probability of achievement may be diminished.

The drafting lesson is for sellers to thoughtfully consider the risk allocation embedded in the "deductions consistent with GAAP and historical practice" language, which silently assigns every current and future pricing program to the holder.

Where possible, sellers should seek to address each policy line item expressly and define triggers by category and effect — capturing any government-mandated or -benchmarked price reduction and any successor program — rather than by citing a specific rule that may be enjoined, repealed or replaced.

And then there are harder questions to confront in the deal process — for instance, if a buyer signs an MFN agreement that lowers a product's U.S. price or economics, has it breached its commercialization-efforts covenant?

Compliance-with-law provisions likely protect a mandated cut, but any voluntary agreement would be harder to shelter, and Delaware courts will enforce the words the parties chose rather than invoke the implied covenant to reallocate a foreseeable risk.

A workable pairing may be possible: The buyer secures an express carve-out that compliance with a government price program is not a breach, while the seller obtains a net-sales hold-harmless so the resulting price cannot be trimmed to defeat the milestone.

The organizing principle is that control and consequence should rest in the same hands: The party that decides whether to sign an MFN deal, or how to price a reference basket, should bear the measurement consequence.

With the law remaining unsettled and the manufacturer agreements executed to date confidential, the task is not to predict the outcome but to draft so the allocation survives any present or future imagination of MFN. Dealmakers who wait for the rules to settle will be negotiating these terms after the risk has already been priced against them.

Margaux Hall, Branden Berns and Karen Spindler are partners at Gibson Dunn & Crutcher LLP.

Gibson Dunn partner and co-chair of the firm's life sciences practice Ryan Murr contributed to this article.