Navigating Life Sciences Deals Amid Heightened Scrutiny

By **Sarah Hogan, Jenna Ventorino and Stephen Abreu** (March 27, 2026)

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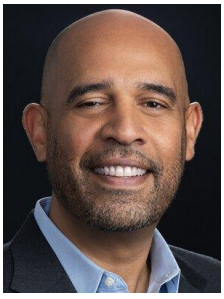

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The pharmaceutical industry has been under heightened scrutiny in Washington, leading to meaningful uncertainty for life sciences companies across the development and commercialization lifecycle.

Pricing reform initiatives, national-security-driven legislation and evolving trade policy are reshaping the landscape and risk calculus for all stakeholders considering life sciences partnering transactions.

This article examines how most-favored-nation, or MFN, drug pricing initiatives, the Biosecure Act and broader market uncertainty are affecting life sciences transactions, and the legal and commercial implications for dealmakers.

Against the backdrop of regulatory uncertainty, life sciences dealmakers should be increasingly focused on anticipating regulatory and transactional risks earlier in the deal process.

By taking steps early, ideally prior to term-sheet development, clients can better position themselves to avoid downstream complications, preserve optionality and structure transactions aligned with long-term strategic objectives.

Renewed Focus on MFN Pricing

The Trump administration's renewed emphasis on MFN drug pricing initiatives has introduced significant uncertainty for biotechnology and pharmaceutical companies in global commercialization strategies.

In May 2025, the administration issued an executive order on delivering MFN prescription drug pricing to patients, directing the U.S. Department of Health and Human Services, in coordination with other agencies, to establish MFN price targets, propose rulemaking and take related actions aimed at lowering drug prices in the U.S.

The administration subsequently sent letters in July 2025 to 17 major drugmakers outlining what a White House fact sheet described as "the steps they must take to bring down the prices of prescription drugs in the United States to match the lowest price offered in other developed nations (known as the most-favored-nation, or MFN, price)."[1]

As stated in the fact sheet, the steps outlined in the letters included, among others, calling on manufacturers to provide MFN pricing for Medicaid patients, and urging companies to stipulate that they will not offer other developed nations better prices on new drugs than prices offered in the U.S.

The fact sheet also referred to "[u]sing trade policy to support manufacturers in raising prices internationally provided that increased revenues abroad are reinvested directly into lowering prices for American patients and taxpayers."

The administration has since announced voluntary agreements with 16 of the 17 manufacturers that received a July 2025 letter, stating that such agreements involve access to MFN drug pricing. The details and terms of the agreements remain undisclosed.

Meanwhile, in late 2025, HHS' Centers for Medicare & Medicaid Services announced three MFN-style models that CMS is implementing, or has proposed to implement, through its Center for Medicare & Medicaid Innovation: (1) the voluntary GENEROUS model, effective Jan. 1 this year, (2) the proposed GLOBE model, and (3) the proposed GUARD model.

Through GENEROUS and the proposed GLOBE and GUARD models, CMS seeks to advance MFN drug pricing policies in Medicaid, Medicare Part B and Medicare Part D, respectively.

Under GENEROUS, pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program can opt to provide supplemental rebates to participating state Medicaid programs on their covered outpatient drugs, with a goal to align Medicaid net prices for those covered outpatient drugs with prices that certain other countries pay.

CMS recently updated the deadline for manufacturers to submit applications, extending it to April 30. CMS said it will hold meetings with interested manufacturers about potential participation in GENEROUS, and will host a town hall in the spring about the model's operational and methodological details.

Manufacturers will have until June 30 to sign a participation agreement with CMS. States seeking to participate in GENEROUS must apply by July 31, and execute a participation

agreement by Aug. 31.

For GLOBE and GUARD, CMS issued proposed rules in December 2025. Under these proposals, if finalized, CMS would implement MFN pricing for certain drugs and biologics by modifying the Inflation Reduction Act's Medicare Part B and Part D inflation rebate requirements.

CMS has stated that the purpose of GLOBE and GUARD would be to test an alternative Part B (for GLOBE) and Part D (for GUARD) inflation rebate calculation for Part B or Part D drugs and biologics subject to the models by using certain international prices to establish a benchmark.

As proposed, initial GLOBE and GUARD implementation would be limited to selected geographic areas.

Several stakeholder comments have expressed concerns about the proposed models from legal, practical and public policy perspectives. It remains to be seen whether CMS will finalize the proposed models and, if so, what changes may be implemented in the final rules as compared to the proposals.

In additional developments, the administration has encouraged expansion of direct-to-consumer distribution models offering drugs at MFN-level prices and has urged Congress to codify certain MFN-related policies.

While these MFN developments to date primarily relate to voluntary initiatives or to proposals that are limited in scope and not yet finalized, the uncertain and rapidly evolving landscape creates strategic challenges for life sciences companies as they navigate current circumstances and plan future activities.

These considerations also are further compounded by uncertainties resulting from the administration's trade policies and tariff measures.

Implications for Global Pricing and Partnering Transactions

As reflected in information issued to date about the GENEROUS model and proposed GLOBE and GUARD models, the various MFN initiatives and proposals involve different methodologies and reference countries for determining international benchmarks and MFN pricing.

But under the different methodologies, MFN benchmarks appear to be tied to the prices of the drug product itself in certain other developed nations, without regard to the identity of the entity selling the product abroad and without regard to whether the company with U.S. commercialization rights is the same party as the entity or entities with commercialization rights in other countries.

As a result, parties pursuing partnering transactions risk the possibility that lower prices achieved by foreign licensees could exert downward pressure on U.S. pricing under an MFN framework. That risk has prompted companies to reassess whether and under what circumstances to enter into split-territory licenses, and, if so, how to structure such arrangements to minimize these risks.

Some potential strategic responses include the following.

Avoiding Ex-U.S. Licenses

A company could choose not to license commercialization rights outside the U.S., retaining control over pricing in all markets where the product is sold.

Of course, this option is not always available, particularly to smaller companies that lack the infrastructure to bring a product to market outside of the U.S. or that need to partner ex-U.S. rights in order to raise nondilutive capital.

Strategically Licensing to Specific Markets

If ex-U.S. licensing is pursued, a company might prioritize markets that are expected to command higher prices, such as Japan or major European countries, including France, Germany, Italy, Spain and the U.K. This could potentially mitigate downward pressure on the MFN benchmark price.

Companies also could seek to prioritize markets that, at least to date, have not been included as applicable reference countries in MFN initiatives and proposals, although those applicable countries could change going forward.

Considering Co-Commercialization Deals

Co-commercialization arrangements afford parties shared governance and economics,

which may make MFN exposure more manageable than in a straight out-license model.

Bespoke Solutions

Although this is a rapidly changing landscape, other deal-specific, contractual protections might be available on a case-by-case basis, subject to compliance with local competition law and mandates.

Deal counsel can work with regulatory counsel to craft a solution specific to each situation that ensures consideration of and supports compliance with the fast-moving legal landscape.

As another example, even in a worldwide license, licensees are considering deal terms that minimize their MFN risk or share MFN impact with licensors if MFN policies negatively affect U.S. pricing.

When confronted with these deal terms, it is important for licensors to consider whether such terms would require them to disproportionately bear the risk of MFN impacts, risks that are likely to be beyond the licensor's control.

Biosecure Act and National Security Risk

Overlaying these pricing and trade dynamics is a heightened focus on national security in the biotechnology sector.

The Biosecure Act, which became law in December 2025, affects life sciences companies that rely on federal funding, global supply chains or cross-border collaborations.

The Biosecure Act prohibits federal agencies from contracting with, purchasing certain equipment or services from, or providing loans or grants to certain companies that the U.S. government determines pose a national security risk, specifically, entities the law defines as "biotechnology companies of concern."

The scope of the legislation is broad and could affect a wide range of activities, including research collaborations, clinical trial management, manufacturing and supply chain sourcing.

In addition to restricting access to federal grants and contracts, the Biosecure Act

emphasizes supply chain transparency, ownership disclosure and data security, reflecting broader concerns about foreign access to critical biomedical infrastructure.

For life sciences companies, the Biosecure Act introduces new compliance challenges. Companies must conduct thorough due diligence on current and potential partners' ownership structures, supply chain partners and data management practices.

The Biosecure Act may also prompt a shift toward domestic sourcing and increased investment in cybersecurity infrastructure. Additionally, among other mandatory reviews, reports, evaluations and regulatory issuances, the Biosecure Act requires that multiple federal agencies issue implementation guidance and determinations related to designating, reviewing and updating the list of biotechnology companies of concern.

Accordingly, the landscape continues to evolve and will require ongoing monitoring.

Biotechnology companies should consider the following.

Supply Chain Considerations and Contractual Terms

Strategically, companies should review ownership structures and supply chain relationships thoroughly and early in a transaction process to identify potential exposure and mitigate risk. Companies should also consider incorporating representations, warranties and indemnities addressing Biosecure Act compliance in new agreements.

Discussions With Federal Agencies

Proactive engagement with federal agencies to clarify compliance expectations and mitigate risk is also recommended. The Biosecure Act underscores the intersection of national security and biotechnology, requiring companies to balance innovation with robust risk management.

Exit Provisions

Companies may consider including specific provisions in commercial agreements to facilitate a rapid exit if a partner is designated a biotechnology company of concern under the Biosecure Act.

Ongoing Assessment and Monitoring

It will be important for companies to assess current implications of the Biosecure Act's provisions as well as ongoing developments, forthcoming guidance and opportunities for input related to the government's implementation and enforcement of the Biosecure Act.

Structuring Deals Amid Market Uncertainty

These regulatory developments are unfolding against a backdrop of broader geopolitical volatility and evolving market conditions. As a result, life sciences companies are being asked to negotiate transactions that not only reflect current realities but also anticipate future potential regulatory and commercial disruption.

Flexibility has become a critical design feature in deal architecture. For example, companies are reevaluating whether to retain broader geographic rights, pursue staged or option-based collaborations, or sequence ex-U.S. partnering transactions to preserve optionality until greater regulatory clarity emerges.

In some cases, this has meant delaying long-term alliances in favor of incremental or milestone-based structures that allow parties to adapt as policy and market conditions evolve.

From MFN pricing initiatives to restrictions driven by national security under the Biosecure Act, the regulatory and commercial environment for life sciences transactions is becoming increasingly complex.

These developments underscore the importance of identifying pressure points early, stress-testing assumptions and structuring transactions that are resilient to policy shifts and market uncertainty.

By taking action at the outset of a transaction, rather than after key terms have been set, companies will best be able to mitigate the impact that external uncertainties will have on their transaction terms.

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[1] https://www.whitehouse.gov/fact-sheets/2025/07/fact-sheet-president-donald-j-trump-announces-actions-to-get-americans-the-best-prices-in-the-world-for-prescription-drugs/.