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Navigating Life Sciences Deals Amid Heightened Scrutiny

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Executive summary: The life sciences industry is operating under heightened Washington scrutiny, with pricing reform initiatives, national security-driven legislation, and evolving trade policy reshaping the landscape and risk calculus for all stakeholders. Three key forces driving structural change in how deals in the industry are conceived, negotiated and documented include the following:

- **MFN drug pricing initiatives:** The Trump administration's renewed emphasis on most-favored-nation (MFN) drug pricing initiatives has introduced significant uncertainty for biotechnology and pharmaceutical companies in global commercialization strategies.
- **The Biosecure Act:** 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 by prohibiting federal agencies from contracting with, purchasing certain equipment or services from, or providing loans or grants to entities the law defines as "biotechnology companies of concern."
- **Broader market uncertainty:** These regulatory developments are unfolding against a backdrop of broader geopolitical volatility and evolving market conditions, requiring companies to negotiate transactions that not only reflect current realities but also anticipate future potential regulatory and commercial disruption.

For venture capital investors and business owners active in the life sciences space, understanding and proactively addressing these forces is no longer optional. It is a prerequisite for sound dealmaking.

Key take-home: Life sciences dealmakers must anticipate regulatory and transactional risks earlier in the deal process – ideally before term sheet development – to preserve optionality, avoid downstream complications and structure transactions aligned with long-term strategic objectives.

The landscape: What you need to know

MFN drug pricing initiatives and potential implications for partnering transactions

Among several recent developments related to MFN drug pricing initiatives, in May 2025, the administration issued an executive order directing the US Department of Health and Human Services (HHS), in coordination with other agencies, to establish MFN price targets, propose rulemaking and take related actions aimed at lowering drug prices in the US. Additionally, in late 2025, HHS's Centers for Medicare & Medicaid Services (CMS) announced three MFN-style models that CMS is implementing, or has proposed to implement, through its Center for Medicare & Medicaid Innovation – the voluntary GENEROUS model (effective January 1, 2026, though CMS is still accepting applications), the proposed GLOBE model (issued as a proposed rule and to date not finalized) and the proposed GUARD model (issued as a proposed rule and to date not finalized) – in efforts to advance MFN drug pricing policies across Medicaid, Medicare Part B and Medicare Part D, respectively.

As these MFN pricing policies take shape, and as more details emerge on whether and to what extent they may or may not be implemented and/or modified going forward, companies engaged in partnering transactions face the risk that lower prices achieved by foreign licensees in certain countries potentially could exert downward pressure on US pricing under an MFN framework. This 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 MFN-related pricing exposure.

Strategic responses available to dealmakers to mitigate MFN-related pricing considerations:

- Permitting licensees to buy out licensors' retained regional rights in split-territory transactions if the MFN risk becomes

material.

- Retaining control over pricing by not licensing commercialization rights outside the US, although this option may not be feasible in light of other transactional or strategic goals.
- If ex-US licensing is pursued, prioritizing markets expected to command higher prices, such as Japan or major European countries, including France, Germany, Italy, Spain and the UK, to potentially mitigate downward pressure on the MFN benchmark price
- Prioritizing 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 arrangements, which afford parties shared governance and economics and may make MFN exposure more manageable than in a straight out-license model.
- Pursuing bespoke, deal-specific contractual provisions and protections crafted by deal counsel in coordination with regulatory counsel to ensure compliance with the fast-moving legal landscape.

The Biosecure Act: National security meets biotech

By prohibiting federal agencies from contracting with, purchasing certain equipment or services from, or providing loans or grants to companies that the US government has designated as "biotechnology companies of concern" under the terms of the Biosecure Act, the Biosecure Act has the potential to affect a range of activities, including research collaborations, clinical trial management, and manufacturing and supply chain sourcing. The act places particular emphasis on supply chain transparency, ownership disclosure and data security, reflecting broader concerns about foreign access to critical biomedical infrastructure.

Steps for addressing Biosecure Act compliance risks:

- Review ownership structures and supply chain relationships thoroughly and early in a transaction process, and consider incorporating representations, warranties and indemnities addressing Biosecure Act compliance in new agreements.
- Consider including specific provisions in commercial agreements to facilitate a rapid exit if a partner is designated a biotechnology company of concern.
- Keep up to date on the current implications of the Biosecure Act's provisions, including ongoing developments, forthcoming guidance and opportunities for input related to the government's implementation and enforcement.

Looking ahead: Structuring deals for resilience

Flexibility has become a critical design feature in deal architecture. Companies are reevaluating whether to retain broader geographic rights, pursue staged or option-based collaborations, or sequence ex-US 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.

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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