Emerging considerations for loan documents in life sciences

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AUGUST 5, 2026

As private credit deal flow in the life sciences industry grows rapidly, such financings require careful, expert-driven due diligence and nuanced drafting of documents to adequately account for emerging regulatory and market trends.

Lenders that closely track these market and regulatory developments are better positioned to preserve downside protection while supporting successful financing relationships.

This article explores:

•how developments across key regulatory agencies, including the U.S. Department of Health and Human Services ("HHS") and Food and Drug Administration ("FDA"), have impacted pharmaceutical, medical device, and vaccine research and approvals;

- the critical role of evaluating and protecting intellectual property ("IP") for biotechnology companies seeking private credit support; and
- how these life sciences considerations can inform credit agreement protections for lenders.

1. Emerging life sciences regulatory and market trends

Federal agencies such as the FDA have long relied upon institutional resources, staffing, and partnerships with the scientific community when reviewing new drug or medical device applications for safety and efficacy. While the 2025 federal government shutdown delayed the FDA's review of these applications, the agency has faced several headwinds that similarly pose risk to approval timelines and process predictability.

For instance, the FDA's Center for Biologics Evaluation and Research experienced net staffing losses in FY25 of 224 employees, and the Center for Drug Evaluation and Research has similarly faced staffing tension, as revealed by their of net loss of 1093 employees in FY25 (Center for Drug Evaluation and Research & Center for Biologics Evaluation and Research Net Hiring Data (FY 2023-2027), FDA, 7/9/2026, https://bit.ly/44SHOPJ) — particularly amidst the growth of artificial intelligence in research and initial new drug submissions.

Relatedly, the agency has faced several changes to leadership in late 2025 and early 2026, including the appointment of a new Acting Director of the Center for Drug Evaluation and Research in December 2025 (FDA Announces Leadership Appointments at Center for Drug Evaluation and Research, FDA, 12/3/2025, https://bit.ly/3RZV16q) which has brought additional uncertainty to agency priorities ("FDA's leadership void leaves biotech with renewed 'uncertainty'," BioPharma Dive, 5/13/2026, https://bit.ly/4bzzlzt).

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Taken collectively, these trends reflect a potential "moving target" for life sciences companies navigating new clinical trials, anticipated FDA review procedures (and timeline), as well as data standard expectations for early-stage research to be commercialized.

This uncertainty has been compounded by the agency's uncertain ongoing reliance on objective advisory committees, which have traditionally brokered input from cross-industry scientific experts when the FDA evaluates new approval submissions. ("FDA Abandoning Expert Reviews: Implications for Drug Developers and Quality Professionals," Pharmaceutical Technology, 9/12/2025, https://bit.ly/4x2hK0x)

The research ecosystem has similarly experienced tension as historical federal funding avenues become more limited. Amidst federal grant funding cuts across agencies in 2025, HHS wound down its mRNA vaccine development activities under the Biomedical Advanced Research and Development Authority last summer.

HHS' emerging scrutiny of vaccine research, safety, and efficacy has both limited available funding for certain breakthrough products (absent private capital involvement) and had a "trickle-down" effect to the FDA. Of particular relevance, FDA has taken an increasingly rigorous approach when reviewing vaccine application and trial data, even for historical trials under which sponsors had previously communicated with regulators on trial structure and preliminary data readouts. These changes have compounded uncertainty for life sciences companies focused on vaccine development and mRNA research in particular.

Finally, the United States' relationship with the global research community remains in flux. Federal tariff policy has created pressures on supply chains relying on ex-U.S. manufacturing and distribution partners.

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The U.S. Department of Justice's Data Security Program implementing Executive Order 14117 placed further limits on data transfers with "countries of concern," such as the People's Republic of China, that are traditionally essential for successful research partnerships. Drug sponsors in particular face these pressures while simultaneously grappling with proposed most-favored-nation ("MFN") drug pricing demands from the federal government, which further tightens revenue growth and predictability.

2. IP value is more dynamic

IP has always been central to life sciences lending. Beyond patents, life sciences companies derive IP value from regulatory exclusivity, know-how, data, platform technology, licenses, collaborations and royalty streams.

Unlike more traditional collateral, these assets present unique challenges for lenders: Their value can shift rapidly based on regulatory developments, competitive dynamics, and third-party conduct largely outside the borrower's control. For example, a licensor's termination notice, a collaboration partner's failure to commercialize, a contract manufacturer's inability to support tech transfer, or a royalty obligor's assertion of offsets can affect collateral value even if the borrower remains compliant with its own obligations.

Recent developments underscore the importance of this dynamic. Patent-listing scrutiny at the FDA, challenges to exclusivity strategies, accelerated generic or biosimilar competition, MFN pricing requirements and other product-specific pricing initiatives can affect IP value before the expected patent cliff. For lenders, these pressures mean that a borrower's IP portfolio may not provide the collateral cushion that patent diligence alone would suggest.

The complexity of life sciences IP structures is increasing as more borrowers derive meaningful value from royalty streams, platform technology, proprietary data, manufacturing know-how, AI-enabled discovery tools and complex licensing arrangements. These assets may not fit neatly into customary collateral analysis.

A royalty stream depends on license scope, royalty reductions, buyback rights or the conduct of a third-party commercial partner. A platform company may depend on datasets, algorithms, regulatory data packages or trade secrets rather than a single patent estate. A borrower using AI-enabled tools may need rights not only in software, but also in inputs, outputs, model improvements and data-use arrangements.

These complexities have direct implications for lenders. Effective IP diligence and documentation do not merely address IP ownership — they analyze the borrower's practical ability to generate revenue from the assets the lenders underwrote. Agreements should reflect this more nuanced risk profile, and lenders who take a thoughtful, bespoke approach to definitions, representations, covenants, and defaults are better positioned to protect their investment as market or regulatory conditions shift.

3. Lender opportunities for life sciences loan documents

We advocate for closely tailored loan documents that address the specific — and uncertain — regulatory environments in which their life sciences borrowers operate.

Loan document provisions should match the product and IP definitions to the specific assets underlying the financing. For example, lenders may be well-served to expand the concept of "material intellectual property" to capture the full range of IP assets that drive repayment capacity, particularly for platform companies, royalty-dependent borrowers, or AI-enabled enterprises where value flows from data, algorithms, and contractual rights rather than a traditional patent estate.

When crafting covenants and defaults, credit agreements should also identify probable and predictable occurrences that — were they to occur — would reasonably be expected to undermine the borrower's value proposition and its ability to repay its loan obligations.

Examples will be specific to each situation, but may include:

- FDA refusal to review new drug or device applications,
- material and adverse changes in FDA or HHS research policy that substantially curtail approval likelihood,
- material impairment of IP-derived collateral value before expected patent or exclusivity expiry,
- material supply chain disruptions,
- clinical trial delays due to restricted data transfers with "countries of concern," or
- federally-imposed MFN pricing (particularly for less diversified portfolios).

Credit agreements that have not been closely crafted to the relevant life sciences business may only require notice of such events to lenders — or may not even require notice — instead relying on financial covenants that may be a lagging indicator of impairment or deferring to the borrower's judgment as to whether such events might reasonably be expected to cause a material adverse effect.

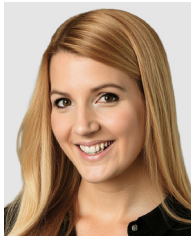
These approaches may be insufficient to adequately protect lenders' investments because evolving policy and agency priorities, or material operational issues, can undermine transaction value quickly.

It is also important to delineate specifically which issues may be remedied, and on what timeline. For instance, material changes to federal agency research policy may not be curable in the immediate term — so lenders to relevant borrowers will want to consider whether an extended cure period is appropriate, or whether certain regulatory developments should trigger immediate consequences.

In some cases, delay may not be viable: trial data can become stale, exclusivity windows can close, and competitive dynamics can shift irreversibly. The goal is not to turn every regulatory or IP development into a default, but to ensure the credit agreement gives lenders visibility and protection when the rights that support repayment are challenged, narrowed, transferred, or otherwise impaired.

As life sciences lending continues to expand, lenders who adapt their approaches to diligence and documentation to reflect the full complexity of relevant collateral will be better positioned to protect their investments by addressing regulatory uncertainty and developmental and operational hurdles.

About the authors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This article was first published on Reuters Legal News and Westlaw Today on August 5, 2026.