



Insight

New COINS Act Regulations Restricting Biotechnology Investment Leave Critical Questions Unanswered

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Executive Summary

- The U.S. Department of the Treasury released a notice of proposed rulemaking to implement the Comprehensive Outbound Investment National Security (COINS) Act, which establishes a framework for evaluating and restricting certain U.S. investments involving countries of concern, including China; Congress identified five technology categories for regulation and gave Treasury the authority to add others.
- The proposed rules would apply to certain equity acquisitions, financing arrangements, joint ventures, and other investments involving covered foreign persons engaged in the specified activities; this rule offers little justification for treating ordinary pharmaceutical development as a prohibited technology.
- The resulting regulatory framework imposes categorical restrictions on a scientifically diverse industry; these restrictions risk sacrificing investment opportunities and regulatory predictability for national security benefits that remain insufficiently substantiated, while leaving investors to navigate distinctions that Treasury has not adequately drawn.

Introduction

The U.S. Department of the Treasury [proposed](#) a regulation extending restrictions on American outbound investment to biotechnology, potentially prohibiting investments in

foreign companies developing everything from cancer treatments to vaccines and gene therapies. The regulations implement the Comprehensive Outbound Investment National Security (COINS) Act, enacted in December 2025, which established a statutory framework for restricting certain U.S. investments involving countries of concern, including China. Building upon an existing investment security program, the law authorizes Treasury to prohibit certain transactions involving sensitive technologies while requiring notification of others.

Congress identified five technology categories for regulation, including semiconductors, artificial intelligence, quantum information technologies, high-performance computing, and hypersonic systems. Biotechnology was not among them, but Congress authorized Treasury to designate additional technologies associated with the military, intelligence, surveillance, or cyber-enabled capabilities of countries of concern. Treasury has now exercised that authority, proposing to classify a broad range of pharmaceutical activities as prohibited technologies.

The proposed rules would apply to certain equity acquisitions, financing arrangements, joint ventures, and other investments involving covered foreign persons engaged in the specified activities. They would not establish a routine preapproval process; rather, investors would generally be responsible for determining whether their transactions are permissible. The regulations are not yet final, with Treasury accepting public comments through December 7 before issuing binding requirements.

Although Treasury possesses the authority to expand the program, its proposal offers little justification for treating ordinary pharmaceutical development as a prohibited technology. The result is a regulatory framework that imposes categorical restrictions on a scientifically diverse industry while leaving investors to navigate distinctions the agency has not adequately drawn.

Defining the Threat Before Restricting the Investment

In soliciting public comment, Treasury specifically asks whether the pharmaceutical provision should be limited to advanced or frontier technologies and whether its broader biotechnology definitions should be narrowed. The department also acknowledges that its restrictions could produce public-health risks or harm U.S. businesses, potentially generating consequences contrary to the administration's stated objectives.

These acknowledgments are important. Treasury has proposed placing an expansive category of pharmaceutical activities within an outright investment prohibition while simultaneously seeking guidance on how that category should be defined. Simply restricting

coverage to advanced technologies would not necessarily resolve the problem. Scientific sophistication is not a reliable proxy for military utility. Many of the most advanced pharmaceuticals are intended to treat cancer, genetic disorders, and other serious diseases. Their development may employ complex biological systems without conferring any identifiable military advantage.

The proposed rule remains subject to revision, and its eventual impact will depend on how Treasury responds to public comments and refines the biotechnology provisions before finalization. The department has an opportunity to establish clearer technical definitions, distinguish activities warranting prohibition from those potentially appropriate for notification, and provide more predictable compliance standards. It should also more thoroughly examine the investments and commercial opportunities that could be lost.

More fundamentally, Treasury should establish a credible connection between the specific pharmaceutical activities it seeks to restrict and the national security threats those restrictions are intended to mitigate. An expansive conception of national security risks converting a targeted justification for government intervention into a general authority to restrict investment across economically significant industries.

Treasury may ultimately narrow its approach, but the current proposal falls short of that standard. Before finalizing its regulations, the department should draw the distinctions it has effectively left to investors and demonstrate why the market restrictions it proposes are warranted. Without those changes, the rule risks sacrificing investment opportunities and regulatory predictability for national security benefits that remain insufficiently substantiated.

The Breadth of the Proposed Prohibition

Under proposed Section 851.226(r) of the regulation, prohibited technologies restricted for outbound U.S. investment include the development, engineering, or use of biological systems to modify, enhance, produce, or control certain compounds and materials. Some categories are narrowly defined, including restricted biological agents and toxins, explosive precursors, and specialized materials; others are considerably broader. Section 851.226(r)(4) encompasses pharmaceutical compounds, including small molecules, vaccines, blood products, cell and gene therapies, monoclonal antibodies, and other therapeutic proteins, along with their delivery mechanisms. Additional provisions cover biological sequencing technologies, bioinformatics tools, laboratory automation, and certain biomanufacturing equipment.

Although the pharmaceutical provision requires the involvement of a biological system and

does not automatically encompass every drug development activity, its scope is substantial. The provision does not, however, require an identifiable military application or any demonstration that a particular pharmaceutical activity poses a national security threat. Other provisions incorporate technical thresholds or military end-use limitations to distinguish covered activities. The pharmaceutical provision offers no comparable distinction.

This is more than a semantic difference. Treasury proposes classifying these activities as prohibited technologies rather than subjecting them to the less restrictive notification requirements available elsewhere in the framework. A company developing an innovative cancer therapy could consequently trigger the same investment prohibition as an entity developing biological technologies with direct military applications.

One important limitation to the proposal's immediate commercial reach seems to be its treatment of conventional pharmaceutical licensing agreements. Arrangements in which companies exchange development or commercialization rights for upfront payments, milestones, and royalties generally fall outside the definition of covered transactions. These deals have accounted for much of the recent growth in pharmaceutical partnerships between U.S. and Chinese companies. According to IQVIA, [40 percent](#) of the assets in-licensed by large pharmaceutical companies in 2025 had a Chinese licensor, up from less than 30 percent in 2024.

While much of the ultimate impact rests on the real interpretation of what constitutes a covered transaction, most of the prominent licensing agreements driving recent U.S.-China pharmaceutical collaboration seem to not be directly prohibited. While meaningful, this distinction does not excuse the restrictions imposed on other financing arrangements. Equity investments, qualifying joint ventures, and other financing agreements could still be prohibited, limiting opportunities for U.S. companies to participate in the next phase of innovative pharmaceutical development. The fact that many existing commercial arrangements seem to remain permissible does not establish that further restrictions are necessary or beneficial.

Regulatory Uncertainty and Its Commercial Consequences

The consequences of Treasury's broad definitions are magnified by the program's regulatory structure. Under proposed Section 851.104, investors must undertake reasonable and diligent inquiries into relevant facts before entering potentially covered transactions. For biotechnology investments, this could require examining a company's research programs, manufacturing processes, technology platforms, and commercially sensitive development pipelines. The challenge is not simply determining what a biotechnology company does, but

whether its activities satisfy a regulatory definition whose boundaries may be difficult to interpret.

Consider a U.S. venture capital firm evaluating an equity investment in a Chinese biotechnology company developing a monoclonal antibody for oncology. The transaction could be prohibited because of the company's pharmaceutical development activities, regardless of whether the investment has any discernible military implications. The investor would bear responsibility for determining whether the transaction is covered and could face significant civil penalties or compelled divestment for a violation.

These assessments also raise questions about Treasury's institutional expertise and administrative capacity. Treasury administers the outbound investment program through its Office of Investment Security and has consulted other federal agencies in developing the proposal. Yet the regulations do not establish a dedicated mechanism for incorporating pharmaceutical expertise into transaction-specific interpretations or enforcement decisions.

In 2025, the National Security Commission on Emerging Biotechnology [identified](#) deficiencies in federal biotechnology expertise, recommending expanded scientific training, specialized personnel, and improved access to appropriately cleared experts. These findings do not establish that Treasury lacks qualified personnel, but they illustrate the difficulty of asking an investment-security agency to interpret complex pharmaceutical activities, particularly when the governing definitions lack precision. Even substantial scientific expertise cannot compensate for an unclear regulatory standard.

Treasury proposes allowing investors to request confidential, nonbinding feedback on prospective transactions. But the department would not be obligated to respond, could modify or revoke its feedback, and would not be bound by its interpretations in subsequent enforcement proceedings. A discretionary national interest exemption could permit otherwise prohibited transactions, but that process is no substitute for predictable regulatory boundaries.

This creates an uncomfortable asymmetry. Treasury retains substantial interpretive and enforcement discretion, while investors must make consequential decisions without guaranteed access to a binding determination. Companies confronting uncertainty may simply abandon otherwise permissible investments rather than incur additional expenses or accept the possibility of an adverse regulatory finding. The resulting market limitations could therefore extend well beyond transactions expressly prohibited by the rule.

Economic Costs Treasury Has Not Accounted For

Treasury's economic analysis provides an incomplete assessment of these consequences.

The department estimates annual private-sector compliance costs of between \$2.77–\$5.86 million across the entire proposed outbound investment program (not just the biotechnology sector). These estimates encompass expenses associated with diligence, recordkeeping, and information submissions. They do not quantify the opportunities investors forgo because of the proposed prohibitions.

Treasury acknowledges that investors prevented from pursuing preferred transactions may redirect their capital toward less promising opportunities. The resulting economic loss would reflect the difference between the expected return on the prohibited investment and that of the best available alternative. Yet Treasury neither estimates this loss nor provides an assessment of the aggregate value of investments likely to be prohibited.

These omissions are consequential. Preventing U.S. capital from flowing into Chinese biotechnology does not mean that the same capital will necessarily be invested in the United States. Investors may instead direct their resources toward opportunities in other foreign markets, pursue less productive investments, or decline to deploy capital altogether. Even when alternative domestic alternatives are available, there is little reason to presume they will offer comparable returns or access to similarly promising scientific developments.

The consequences also extend beyond investors' financial returns. An investment in a foreign biotechnology developer can establish commercial relationships that eventually support U.S. clinical research, drug development, and commercialization. Prohibiting the initial transaction could foreclose some of these downstream opportunities, even if other partnerships, including conventional licensing, remain permissible.

Regulatory uncertainty adds another layer of potentially unmeasured costs. Investments abandoned because of ambiguous definitions, transactions restructured to avoid enforcement exposure, and commercial relationships never pursued may not be captured in Treasury's analysis. These effects are particularly difficult to assess when the department itself has not established clear boundaries for the activities it proposes to prohibit.

Treasury also has not conducted a breakeven analysis, explaining that it continues collecting information about potential costs and benefits. Although national security benefits may be difficult to quantify, difficulty measuring a benefit does not establish its magnitude. When the government proposes restricting otherwise lawful commercial activity, identifying a potential security concern should not suffice as evidence that the intervention's benefits justify its costs.

Without a more complete assessment of forgone investments and their consequences, Treasury has provided little basis for determining whether the proposed biotechnology

restrictions represent a worthwhile economic tradeoff.