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Alert | Life Sciences & Medical Technology

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2 Tracks, 1 Enterprise Strategy: US National Security Policy is Changing Life Sciences Competition with China

Go-To Guide:

- **Capability control, not another list.** U.S. regulations are linking R&D, clinical evidence, manufacturing, capital and licensing, IP, and supply chains. The BIOSECURE Act is one leg, but the larger question is where capability is created, financed, validated, and transferred.
- **The two tracks converge. The Food and Drug Administration** is working to expedite U.S. development and manufacturing while trade and national security rules narrow selected China-linked dependencies.
- **Act at the asset level.** Stakeholders may wish to build one fact base for data provenance, manufacturing, funding, and IP; screen China-linked deals before the term sheet; and preserve domestic or allied capacity without assuming friend-shoring equals statutory onshoring.
- **Structure deals for bilateral closing risk.** Cross-border transactions may face tightening U.S. investment and licensing reviews alongside heightened Chinese outbound investment, data, and human genetic resource controls (Decree No. 837); stakeholders should consider designing term sheets, conditions precedent, and outside dates to survive shifting parameters on both sides.

U.S. life sciences policy toward China is shifting from list-based compliance to capability control**.** FDA pilots, trade measures, outbound-investment rules, research-security policies, patent proposals, and the BIOSECURE Act increasingly operate as one architecture. Taken together, these programs and laws work to accelerate U.S. discovery, trials, and manufacturing while limiting channels through which capital, data, IP, and know-how might strengthen a strategic competitor. For senior leaders at life sciences companies, manufacturing location, data provenance, research funding, IP ownership, and transaction structure may impact both restrictions and access to benefits. National security is becoming a product-development and capital-allocation variable. Our prior GT Alert addresses BIOSECURE and Section 1260H procurement mechanics.

The Accelerant Track: Regulatory Time Is Becoming Industrial Policy

The competitive side of U.S. policy has become more concrete in 2026. The U.S. Food and Drug Administration (FDA)'s Operation TrialBlazer, announced June 22, 2026, is a Department of Health and Human Services (HHS) roadmap that aims to keep early clinical research in the United States. For sponsors, one important component of the roadmap is the proposed expedited investigational new drug (IND) pilot program, which would establish a network of qualified research institutions — academic medical centers, healthcare networks, contact research organizations (CROs), and similar organizations — to partner with sponsors on first-in-human protocols and support rolling IND submissions.

The FDA's Commissioner's National Priority Voucher program provides an accelerated review pathway for select products aligned with national priorities, including domestic manufacturing and supply chain resilience. FDA's PreCheck pilot, established under Executive Order 14293 on domestic production of critical medicines, gives certain new U.S. facilities earlier agency engagement and a more predictable path through facility readiness and application review. FDA received more than 80 requests during the Feb. 1, 2026, to March 1, 2026, application window and selected seven participants for the pilot on June 29, 2026. Two of the seven participants are cell and gene therapy manufacturers, and another participant, Kyowa Kirin, Inc., is a U.S. affiliate of a Japanese company.

Not every company will receive a faster pathway. Some of these pilot programs are selective, voluntary, or still evolving. That asymmetry matters: mandatory restrictions arrive on published dates, while many competitive benefits require a company to apply, commit capital, negotiate an agreement, or design a program before a deadline. Waiting for the rules to become final may stymie companies from capturing the corresponding U.S. option.

This is a change in the economics of location. The federal government is not simply telling life sciences companies to reduce their China exposure; it is increasingly working to make a U.S. alternative faster, more predictable, or more valuable. For senior management, the relevant comparison may no longer be China cost versus U.S. cost. Instead, management may wish to compare the relative cost and speed advantages available in China versus the combined U.S. value of regulatory time, tariff treatment, government eligibility, supply resilience, and strategic optionality.

The Restrictive Track: Decisions That May Carry China Risk

Where Clinical Evidence and Biological Data are Generated

Language from the House FY2027 Agriculture-FDA report would limit FDA consideration of certain China-, Russia-, Iran-, or North Korea-site clinical data for IND-related purposes. Though this language has not been enacted or included in the bill text, sponsors may wish to identify which programs would require a bridging cohort, multiregional redesign, or qualifying-site re-run. For advanced therapeutics,

FDA scrutiny of trials sending U.S. participants' living cells abroad and Department of Justice (DOJ) treatment of genomic data and biospecimens under the Data Security Program may increase the importance of site- and dataset-level provenance in asset valuation and diligence.

Manufacturing Location and Domestic Capacity Considerations

The administration's April 2026 Section 232 pharmaceutical proclamation imposes tariffs of up to 100% on covered patented pharmaceuticals and associated ingredients. However, a larger group of affected pharmaceutical companies will become subject to the tariffs on Sept. 29, 2026. Commerce-approved U.S. onshoring may reduce the additional duty rate to 20%, and qualifying onshoring paired with an HHS most-favored-nation (MFN) pricing agreement may nullify that duty through Jan. 20, 2029. Generics and biosimilars currently fall outside of the covered scope. For complex products, companies may wish to model technology transfer, comparability, validation, supplements, and capacity against filing and launch calendars in an effort to avoid supplier issues.

Structure for China-linked Licensing, Investment, and IP

Current outbound-investment rules do not generally cover biotechnology, but the administration's America First Investment Policy, released in 2025, called for consideration of additional China-related restrictions. Additionally, the enacted Comprehensive Outbound Investment National Security Act of 2025 (COINS Act) in the FY2026 National Defense Authorization Act authorizes the Department of the Treasury to add technology categories by regulation. Biotechnology may therefore enter the regime whether or not the bipartisan Biotech Investment National Security Act (BINSA) is enacted, which makes Treasury rulemaking an important forum for stakeholders. Separate BINSA proposals in the House (H.R. 9102, introduced June 2, 2026) and the Senate (S. 5316, introduced Aug. 6, 2026) would expressly add biotechnology — defined to reach pharmaceutical and biological product development, drug discovery platforms, clinical R&D capability, biologics manufacturing, and related intellectual property and know-how — and make specified pharmaceutical licensing deals, joint ventures, and equity investments with Chinese covered foreign persons subject to Treasury review.

Under the BINSA proposal, an in-license through which a U.S. sponsor acquires China-origin technology may become reviewable, even though the commercial objective is to bring the asset into the United States.

A second, quieter front is patent eligibility and enforceability. The Prohibiting Adversarial Patents Act of 2026 would bar issuance of U.S. patents to specified covered parties and render certain issued patents unenforceable. The Foreign Adversary Patent Disclosure Act would require inventor-level disclosure of specified foreign-adversary affiliations and funding. Neither is current law, but they underscore the potential importance of chain of title, co-ownership, inventor affiliation, and enforcement control for in-licensed technology.

Advanced therapeutics are the stress test. Cell and gene therapy collaborations often move not only patent rights and capital but living cells, vectors, manufacturing know-how, genomic or other omic data, and technical assistance. BINSA's proposed scope would reach biological products, clinical R&D capability, and biologics manufacturing know-how. DOJ's Data Security Program separately treats human genomic data and human biospecimens from which it can be derived as protected categories, although specified clinical-investigation and product-authorization transactions may qualify for exemptions. The result is not a blanket ban; it is convergence risk. The same modality also appears on the accelerant track: two of the seven FDA PreCheck participants selected in June are cell and gene therapy manufacturers. For advanced therapeutics companies, licensing, clinical, data-security, and manufacturing diligence may therefore be relevant to early transaction analysis, including before term-sheet stage.

Federal Research Funding and Restricted-Entity Exposure

The National Institutes of Health (NIH)'s international-component structure and the National Science Foundation's forthcoming FY2027 restricted-entity collaboration policy may impact companies indirectly through universities, federally funded cores, sponsored research, and subrecipient relationships. Sponsors that depend on academic science should consider mapping federal funding and restricted-party status behind material translational programs, not only their direct vendors. They may also wish to confirm that research and material-transfer agreements can absorb new flow-down terms.

China's Response: Near-Term Friction in Deal Architecture and Closing Certainty

China's countermeasure tools may reach life sciences, but Beijing has not adopted a sector-wide mirror image of the U.S. architecture. The more immediate execution issue is State Council Decree No. 837, which took effect July 1, 2026. This decree consolidates China's outbound-investment framework and operates alongside data-security, technology-transfer, export-control, and human genetic resources rules. China's Human Genetic Resources (HGR) administration has moved from the Ministry of Science and Technology (MOST) to the National Health Commission, while separate cross-border data rules may apply to specified data exports. The HGR rules and cross-border data regime therefore matter to transaction execution, even where the outbound-investment filing itself is straightforward.

Decree No. 837 itself reaches direct and indirect overseas investment and expressly preserves separate technology-export, data-transfer, and national security review requirements. For life sciences transactions, a Singapore, Cayman, or other offshore holding structure may not remove China-side regulatory exposure where the underlying asset depends on China-origin R&D, IP, biological data, samples, manufacturing know-how, or key personnel. For diligence purposes, the history of how those capabilities moved offshore may be as relevant as the jurisdiction of the current target entity.

A China-linked transaction may therefore face U.S. scrutiny of capital and capability transfer while the Chinese counterparty separately navigates outbound-investment, data, genetic-resource, or technology controls.

Considerations for Stakeholders

Stakeholders evaluating China-linked life sciences assets, collaborations, or transactions may wish to consider the following:

- **Build one asset-level China exposure map, rather than another vendor list.** For each material program, map the research collaborators and funding, biological samples and data, clinical sites and CROs, patent ownership and inventorship, licenses, APIs and key starting materials, manufacturing sites, investors, federal funding, and federal procurement nexus. Stakeholders may wish to use asset or program as the unit of analysis because that is where value and transition timing sit.
- **Create the three records that cannot be built under deal pressure.** Maintain (i) a site-level clinical and data-provenance record; (ii) a manufacturing and onshoring record that can support tariff, FDA, and supply-chain decisions; and (iii) a defensible chain-of-title and inventor-affiliation record for in-licensed and co-developed IP. Link the federally funded collaborator schedule to the same fact base.
- **Add a national security gate before the term sheet.** Stakeholders may wish to screen any China-linked in-license, out-license, joint venture, new company, platform arrangement, or equity transaction against current law and a 12-to-18-month foreseeable perimeter. From there, they may

wish to put the result into price, conditions, long-stop dates, cooperation covenants, and change-in-law allocation rather than treating it as a post-signing compliance workstream.

- **Re-underwrite the economics of "China speed."** Where China offers a faster or cheaper trial or manufacturing pathway, quantify the bridging, re-run, technology-transfer, tariff, and delay scenarios that would apply if U.S. policy changes. The relevant metric is risk-adjusted time to the next value inflection point, not the current CRO or CMO invoice.
- **Use U.S. accelerants as strategic options.** Identify programs and facilities that may fit TrialBlazer initiatives, CNPV, PreCheck, domestic-manufacturing pathways, or Section 232 onshoring agreements. These mechanisms do not guarantee approval or relief, but early engagement may create optionality that becomes unavailable once a restrictive date or capacity bottleneck arrives.
- **Prepare the board and disclosure narrative before the inquiry.** Management should consider confirming that they are able to explain the strategic rationale for material China exposure, the diligence performed, the alternatives considered, and the transition plan if policy changes. Securities and Exchange Commission risk-factor language, deal-committee materials, and operational mapping may also rest on the same facts.

Key Milestones and the Planning Calendar[1]

Date/Window	Development	Executive Impact
Now/in effect	FDA cell-transfer review; NIH foreign-component structure; existing outbound-investment rules; Section 232 first tranche	Stakeholders may wish to map trial, funding, investment, IP, data, and manufacturing exposure before layering future proposals on top. They should also consider keeping current obligations and forward-looking scenarios distinct but using a common asset-level record.
Aug. 24, 2026	FDA Expedited IND pilot comment period closes	Nearest-term opportunity to shape a program intended to keep first-in-human work in the United States. Phase 1 sponsors and prospective QRIs should consider whether the proposed model raises an operational issue worth noting.
Sept. 29, 2026	Section 232 pharmaceutical tariff: broader tranche	Covered imports from most remaining affected pharmaceutical companies become subject to the new treatment. Stakeholders may wish to consider whether a U.S. onshoring or onshoring-plus-MFN strategy is commercially available and worthwhile.
FY2027	NSF restricted-entity collaboration policy; OMB Uniform Guidance rewrite; FY2027 appropriations cycle	Research-security terms may flow through academic partners; stakeholders should consider tracking the clinical-data proposal as part of IND and transaction planning.
Dec. 18, 2026	OMB initial list of biotechnology companies of concern	Procurement and counterparty risk becomes more concrete. BIOSECURE remediation sequencing is addressed in our separate GT Alert.

[1] The dates in this chart are not all effective dates; several are proposals or implementation milestones. The management question is what decision stakeholders should consider prior to each date, not whether the rule is already binding. In several areas, the practical window for preserving a clinical, manufacturing, or deal alternative closes first.

Date/Window	Development	Executive Impact
By March 13, 2027	Treasury regulations implementing the COINS Act	Central rulemaking for China-linked investment and licensing structures. Biotechnology may be designated by regulation, which means stakeholders should consider scope and comment participation.
Ongoing	BINSA; June 2026 patent bills; China countermeasures and Decree No. 837 implementation	Do not assume enactment, but consider drafting deals so that a changing U.S. or Chinese perimeter does not create unallocated closing, IP, data, or technology-transfer risk.

National Security As an Input Into Life Sciences Asset Value

For stakeholders, a worthwhile objective may be preserving strategic optionality amidst changing regulations. Knowing where exposure sits, proving the provenance of data and IP, structuring deals that can survive a new review requirement, and maintaining credible clinical and manufacturing alternatives before the market prices them as scarce may push that goal forward. Companies that document and redesign cross-border relationships without losing the next development, financing, or launch milestone may earn an advantage in the market.

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