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STRUCTURING CROSS-BORDER BIOTECH DEALS IN THE SHADOW OF US AND CHINA REGULATORY TIGHTENING

The COINS Act, BINSAs, BIOSECURE, and China's Decree
No. 837: What Deal Teams Need to Know Now

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Agenda

The US Trajectory

DOJ Data Security Program (DSP)

The China Trajectory

The Structural Spectrum

Building Flexibility into Term Sheets

What We Don't Know Yet

The US Regulatory Trajectory

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The US Regulatory Trajectory

The COINS Act: The March 2027 Question

- Section 809 allows Treasury to add biotech without new legislation — no ANPRM or NPRM published yet (as of July 20, 2026)
- Congressional pressure: multiple letters to Treasury urging biotech designation. Industry groups have raised concerns about secondary effects of outbound restrictions.
- KEY DEADLINE: Treasury final implementing regulations due March 13, 2027 — 8 months from today
- Practical implication: deals closing H2 2026 through Q1 2027 face a moving target — if Treasury designates biotech before closing, the transaction may require mid-stream restructuring
- Under current Part 850 rules, pure technology licensing is NOT a covered transaction (per Treasury FAQ) — but BINSAs would explicitly override this if enacted
 - Note: Part 850 outbound rules are distinct from CFIUS/FIRRMA inbound framework. The licensing exclusion is specific to Part 850 covered transaction definitions.
 - Action item: build regulatory-change triggers into any term sheet signed before March 2027

The US Regulatory Trajectory

BIOSECURE Act and the Section 1260H Expansion. Note: 1260H list (updated June 2026, includes WuXi AppTec/BGI/MGI) is a statutory pathway into BIOSECURE under §851(f)(2)(A). OMB consolidated BCC list due Dec 2026. Prohibitions await FAR revision (~mid-2028).

- STATUS: DoD expanded 1260H list in 2026; next update timing unknown
- Scope: prohibits federal agencies from (1) contracting with designated entities AND (2) contracting with entities that USE designated biotech equipment/services in performance — creates supply-chain flow-down effect. NOT a general commercial ban or SDN-style blocking.
- Market impact: some boards are declining new China biotech partnerships where counterparty appears on US government lists — based on recent practitioner observations (limited sample)
- Practical implication: even though BIOSECURE applies only to government procurement, the reputational signal is creating "voluntary decoupling" pressure on private-sector deals

The US Regulatory Trajectory

FY2027 NDAA: Hardening the Infrastructure

- H.R.8800 proposes expanding 1260H framework: §1243 (extend to 2035), §1244 ('formal or informal associations'), §1812 (FASC link), §861 (DoD IP rights)
 - House: Initial rule (H.Res.1398) failed June 30 (198-224). House adopted new rule (H.Res.1438) on July 21 (Roll Call 254); began consideration of H.R.8800. H.R.8800 NOT yet passed.
 - Senate: Cloture on motion to proceed to S.4784 failed July 14 (50-46). Senate remains in procedural stalemate.
 - Amendment 756 (add biotech to COINS): submitted but not made in order under new rule. Does not include BINSAs' explicit licensing provisions.

STATUS

House adopted H.Res.1438 July 21; H.R.8800 under consideration but NOT yet passed. Senate stalled. Timeline for conference and final passage uncertain.

Practical Implication

if the expanded 1260H framework passes, companies with "informal associations" to Chinese military-linked entities could face designation — broadening the universe of counterparties that trigger enhanced diligence

The US Regulatory Trajectory

BINSA: Targeting Licensing Directly

- BINSA remains a standalone bill (H.R. 9102); not attached to NDAA in current amendment list
- Would amend COINS to cover pharma licensing — industry now actively discussing whether this captures ALL out-licenses or only those with tech-transfer elements
- If enacted, a pure out-license from a Chinese biotech to a US buyer could become a "covered transaction" — key question: technology transfer vs. merely commercial rights?
- Current status: proposed legislation only; no committee markup scheduled — but the signal matters: deal teams should not assume licensing remains permanently exempt

CFIUS: The Persistent Inbound Risk

- Practical tip: voluntary CFIUS filing increasingly considered where deal affords foreign person access to material nonpublic technical information or sensitive personal data — but requires a US business and covered investment/control, not merely any data-related transaction
- Sensitive personal data, genomic datasets, and critical technologies remain key considerations.
- Potential filing requirements and national security review

Other Signals: Clinical Data and Research Security

- FDA committee report language regarding Chinese clinical data
- Web of Biological Data Act – June 11 - H.R.9307 (proposed bill, June 11) — would create national biological data platform (not yet enacted)
- Operation TrialBlazer: Expedited IND Pilot RFI closes July 22 — focused on accelerating drug identification to first-in-human via QRIs and rolling submissions (US competitiveness/IND reform signal, not a change to FDA acceptance of foreign clinical data)

DOJ Data Security Program

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DOJ Data Security Program

- Operates independently of investment screening — applies regardless of deal structure
- A pure cash licensing deal can still trigger DSP if it involves bulk sensitive personal data flows
 - This catches deal teams off guard: you solved the COINS/BINSA problem by going cash-only, but the data still flows
 - Key insight: DSP compliance is now a commercial differentiator — DSP-ready Chinese biotechs are more attractive licensing partners
- Those that cannot demonstrate DSP readiness face longer diligence timelines and potential deal restructuring

DSP: Prohibited vs. Restricted—A Practical Map

Prohibited Transactions

- Covered data transactions providing country of concern or covered person ACCESS to bulk human genomic/omic data or biospecimens (28 CFR §202.303):
- Example: U.S. party enables Chinese CRO/licensor access to newly generated U.S. patient genomic data (>100 persons) — PROHIBITED even if data is de-identified (de-identification is not an exemption under DSP)
- Bulk human genomic and other 'omic data
- Human biospecimens from which such data could be derived

Restricted Transactions

- Vendor agreements
- Employment agreements
- Investment agreements
- Example: U.S. sponsor enables covered person access to newly generated U.S. Phase III 'omic data (>100 persons) through shared clinical system or CRO workflow — PROHIBITED absent applicable exemption (§202.511)

DOJ Data Security Program: Compliance Considerations

- Selected life-sciences thresholds: >100 US persons (genomic); >1,000 (other 'omic); >10,000 (health data). Other categories (biometric, geolocation, financial, covered personal identifiers) have separate thresholds.
- Covered data transactions providing country of concern or covered person ACCESS to bulk 'omic data/biospecimens: PROHIBITED (not merely restricted)
- Anonymization, pseudonymization, de-identification, and encryption do not automatically place data outside DSP scope — but de-identification may be a condition enabling clinical trial exemption under §202.511(a)(2)
- Clinical investigation exemption (§202.511): narrowly construed. Two distinct prongs: (a)(1) FDA-regulated clinical investigations; (a)(2) post-marketing surveillance (additional conditions apply)
- Main rule effective April 8, 2025; Subpart J (due diligence + audit for restricted transactions) and Subpart K (reporting + recordkeeping) effective October 6, 2025
 - Subpart J: Data compliance program, annual certification (by officer/executive responsible for compliance), independent annual audit (once per calendar year)
 - Subpart K: Recordkeeping (at least 10 years for transactions subject to Part 202), on-demand reporting, with additional auditable recordkeeping requirements for restricted transactions.
- Civil and criminal penalties for violations

The China Regulatory Trajectory

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The China Regulatory Trajectory

Decree No. 837: Early Signals from the First Three Weeks

- Effective July 1, 2026 — now 20 days in force; early practice signals emerging
- What we are observing in practice (as of mid-July 2026):
 - Elevates regulatory framework to State Council level (行政法规). Existing NDRC/MOFCOM departmental rules to be coordinated and revised per official Q&A — not expressly repealed.
- Red-chip restructurings facing longer timelines; companies without offshore structures face a narrowing window
- Expands review to:
 - Regulators scrutinizing indirect investments through offshore platforms (practitioner observation, not statutory language)
 - "Offshore washing" concerns (Cayman, BVI, HK structures) — early practitioner observations; Decree 837 only 3 weeks in effect
- Practitioner estimate: factor additional regulatory timeline for companies without existing offshore structures (timeline varies by case)

The China Regulatory Trajectory

Implications for Cross-Border Biotech Structures

- Greater difficulty establishing offshore holding companies (e.g., Hong Kong or Cayman)
- Early practitioner reports suggest longer review timelines for red-chip restructurings (limited sample — Decree 837 effective only since July 1)
- Potential narrowing window for companies without existing offshore structures (practitioner observation, not regulator-announced policy)

Transaction Structures

- Generally outside Decree No. 837
 - Pure license-out transactions (cash milestones and royalties; no equity)
- May trigger ODI filing/approval procedures; national security review (Art. 15) only where ODI affects or may affect national security
 - Equity consideration (e.g., NewCo shares)
 - Joint ventures
 - Transactions involving acquisition of overseas ownership/control/management rights or related interests (IP transfer alone may trigger tech export control but does not necessarily constitute ODI under Art. 2)
- Uncertain treatment
 - Hybrid structures (e.g., cash + equity milestones or warrants)

The China Regulatory Trajectory

Cross-Border Data Considerations

- Chinese entities should be prepared for U.S. counterparties to evaluate "covered person" status under the DSP
- DSP analysis applies independently of transaction structure
- Potential conflicts with:
 - Human Genetic Resources (HGR) Regulations
 - China Data Security Law
 - Anti-Foreign Sanctions Law
- DSP readiness becoming a commercial differentiator in cross-border collaborations

The Structural Spectrum

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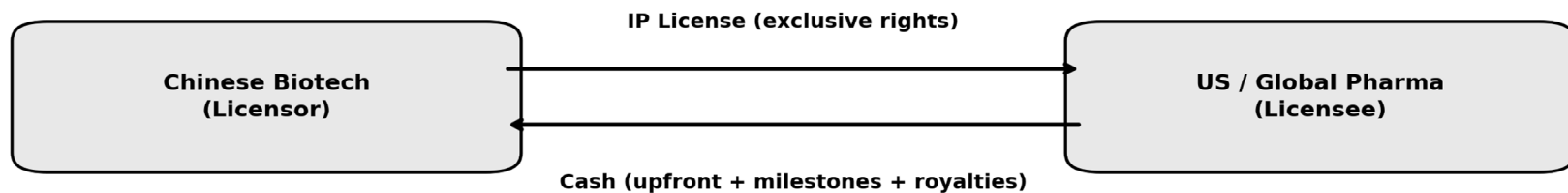
The Structural Spectrum

The Convergence: Deal Design in an Era of Dual-Sided Scrutiny

- Key structural distinction
 - Licensing for cash vs. licensing for equity
 - Increasingly important regulatory variable on both sides of the Pacific
- NewCo structures
 - Chinese biotech licenses assets to an offshore NewCo in exchange for equity
 - US: If biotech designated under COINS (not yet), equity in NewCo could be covered transaction. BINSAs (pending bill, if enacted as drafted) would also cover licensing of prohibited technology.
 - China: Decree 837 ODI review if Chinese entity acquires ownership/control/management rights in offshore NewCo. Tech export control and HGR rules apply independently regardless of ODI classification.
- Regulatory spectrum
 - Pure licensing → least regulatory friction
 - Equity-linked structures (NewCos, JVs) → increasing regulatory scrutiny
 - BINSAs (pending bill): if enacted as drafted, would explicitly cover licensing prohibited technology from a covered foreign person — pure licensing would no longer be exempt from investment screening

Structure A: Pure Cash Licensing

Lowest Regulatory Friction



China Regulatory Exposure

Decree 837: NOT triggered (no outbound investment)

HGR: May apply (if clinical data transferred)

DSP: Independent analysis required for data flows

US Regulatory Exposure

COINS Act: NOT triggered (no equity)

BINSA (if enacted): LOW (commercial rights only)

CFIUS: NOT triggered (no inbound investment)

NET ASSESSMENT

Lowest regulatory friction path — preferred structure where commercial terms permit

Structure B: NewCo / Offshore Vehicle

High Dual-Side Regulatory Exposure



China Regulatory Exposure

Decree 837: LIKELY triggered

(outbound investment via offshore structure)

"Look-through" applies: regulators examine

China-origin strategic assets

Red-chip restructuring: 6-12 month timeline

US Regulatory Exposure

COINS Act: LIKELY triggered

(equity transaction with China-origin IP)

BINSA (if enacted): LIKELY triggered

(licensing for equity)

CFIUS: May apply (US-nexus NewCo)

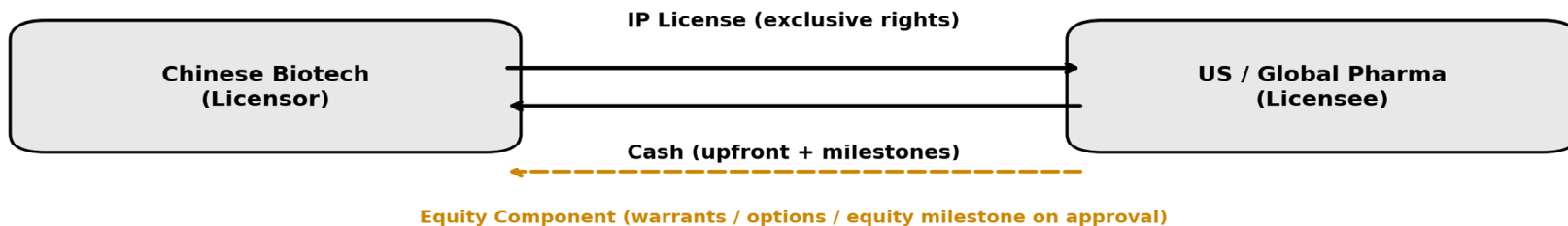
NET ASSESSMENT

Highest dual-side regulatory exposure — requires advance planning

Viable only with: (1) early regulatory engagement on both sides; (2) structural flexibility clauses; (3) 12-18 month timeline assumption

Structure C: Hybrid (Cash + Equity Milestones)

The Grey Zone — Where Most Live Deals Sit Today



China Regulatory Exposure

Decree 837: UNCERTAIN

"Hybrid" not yet addressed in guidance

Equity milestone may = "indirect outbound"

Regulators may "look through" to assess

economic substance

US Regulatory Exposure

COINS Act: UNCERTAIN

Depends on equity threshold

BINSA (if enacted): MEDIUM

Licensing present, but equity blurs the line

Key variable: size and timing of equity trigger

NET ASSESSMENT

The grey zone — viable with structural flexibility clauses and advance monitoring

Recommended approach: draft as cash-only with equity conversion option; include regulatory-change triggers

The Structural Spectrum

Regulatory Spectrum

- Pure licensing → least regulatory friction
- Equity-linked structures (NewCos, JVs) → increasing regulatory scrutiny
- BINSAs (pending bill): if enacted as drafted, would explicitly cover licensing prohibited technology from a covered foreign person — pure licensing would no longer be exempt from investment screening

Data Flows

- Transaction structure and data flows require separate regulatory analyses
- Pure licensing for cash may reduce investment-screening risk
- Accompanying transfers of bulk sensitive personal data require independent DSP analysis
- Data considerations increasingly influence transaction structuring

Building Flexibility into Term Sheets

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Building Flexibility into Term Sheets

Practical Considerations for Deal Teams



Preserve Multiple Structural Pathways

- Draft LOI to permit conversion between cash and equity structures without triggering MAC



Evaluate the Cash/Equity Spectrum

- Map your structure against both US (COINS/BINSA) and China (Decree 837) thresholds
- Assess resulting regulatory exposure on both sides



Build Structural Flexibility

- Regulatory Change Termination Right: either party may terminate if transaction becomes prohibited, creates materially unacceptable regulatory burden, or requires unacceptable mitigation measures
- Structural Pivot Clause: if regulatory change makes agreed structure untenable, parties negotiate restructuring within [30] days
- Regulatory Condition
Precedent: closing conditioned on transaction not being prohibited or subject to materially adverse regulatory requirements under applicable outbound investment rules



Assess Regulatory Risks Early

- CFIUS considerations
- Monitor key regulatory milestones



Plan for Regulatory Change

- Monitor: Treasury ANPRM/NPRM for biotech designation; BINSA committee action; 837 implementing guidance

Building Flexibility into Term Sheets

Data Governance

- Update template agreements for DSP compliance
- Restrict onward transfers of covered data
- Representations and warranties regarding covered person status
- Address:
 - Data access rights
 - Data storage
 - Audit rights
 - Reporting obligations
- Allocate liability for cross-border data flows
- Consider IP ownership and contractual mechanisms to address conflicting US and Chinese requirements

What We Don't Know Yet

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What We Don't Know Yet

United States

COINS Act:
Treasury has NOT published ANPRM — no formal signal on biotech designation yet. Deadline: March 13, 2027.

If designated: prohibited vs. notification-only remains open. Industry groups have raised concerns about secondary effects of outbound restrictions on biotech innovation.

BINSA (H.R.9102): No committee markup scheduled. Standalone bill — distinct from Amendment 756. Explicitly covers licensing of prohibited technology.

FY2027 NDAA: House adopted H.Res.1438 on July 21 (Roll Call 254); began consideration of H.R.8800. H.R.8800 NOT yet passed. Senate cloture failed July 14 (50-46); Senate stalled. Amendment 756 (biotech → COINS) submitted but not made in order.

BIOSECURE:
Implementation timeline for existing designations still TBD. Next 1260H list update: no announced date.

Operation TrialBlazer:
Expedited IND Pilot RFI closes July 22. US competitiveness/IND process reform signal — not a change to FDA acceptance of China-generated clinical data.

Select Committee:
demanded responses from 5 major pharma companies by July 17 on China clinical trials — responses not yet public.

NSF: New policy restricts NSF-funded collaboration with entities/individuals on designated US restricted-party lists. Effective date tied to future guidance/acquisition policy — not a blanket ban on all Chinese institutional collaboration.

What We Don't Know Yet

China

Decree 837: No implementing guidance yet on hybrid structures (cash + equity). Regulators actively "looking through" offshore vehicles. (limited sample, not announced policy) NHC published draft revised HGR Implementing Rules for comment (May 2026) — final version pending.

Red-chip restructurings: facing longer timelines since July 1. Window narrowing for companies without existing offshore structures.

Potential compliance tensions or operational incompatibilities between US DSP requirements and:

- HGR Regulations
- China Data Security Law
- Anti-Foreign Sanctions Law

Overall

Bottom line: significant regulatory uncertainty likely to persist through 2027 and likely beyond (BIOSECURE implementation may extend to mid-2028) — deal teams must plan for ambiguity (note: interim guidance, NPRMs, or enforcement actions could emerge at any time)

The period through March 2027 represents a window where deals may close under current rules — but closing before that date does NOT automatically guarantee grandfathering under future rules

Structural flexibility and regulatory-change provisions are not optional — they are the price of doing cross-border biotech deals today.

Biography



Todd Liao

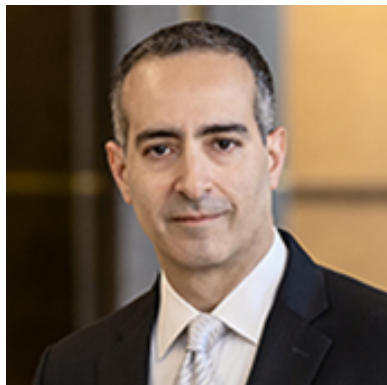
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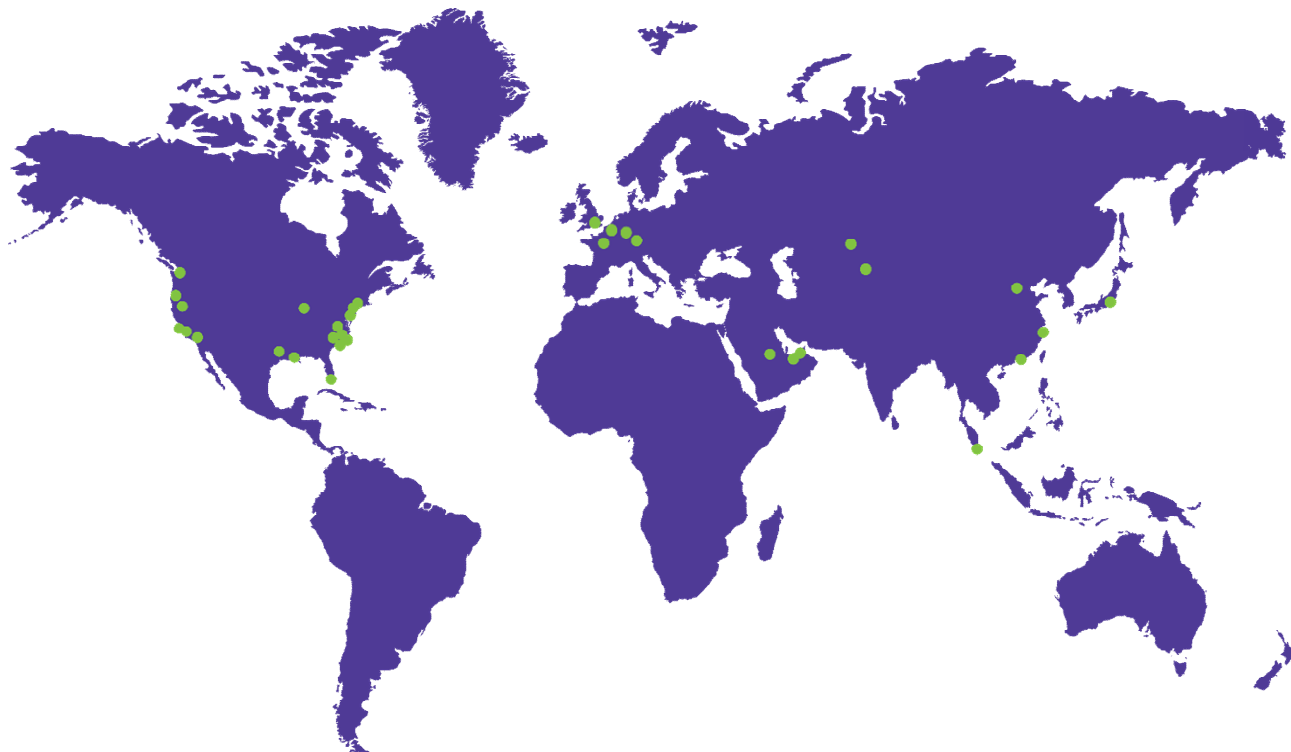
Carl Valenstein focuses his practice on domestic and international corporate and securities matters, mergers and acquisitions, project development, and transactional finance. He works extensively in a variety of industries, including the life sciences, telecom/electronics, renewable energy, and maritime industries, and has worked broadly in Latin America, the Caribbean, Europe, Africa, Asia, and the Middle East.

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