

Impact of the US BIOSECURE Act on Biopharmas, Contract Services and Investors

July 2, 2024



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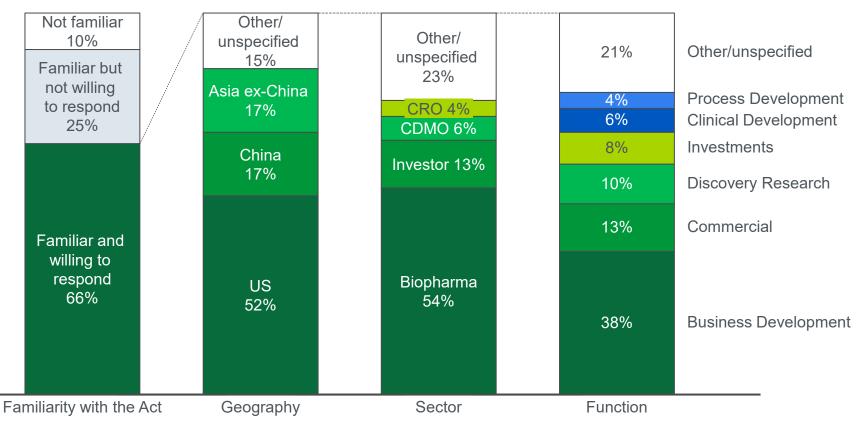
L.E.K. Consulting conducted a survey on the impact of the US BIOSECURE Act; this June 2024 study engaged respondents across different biopharma and services sectors familiar with the Act

Background

- The US BIOSECURE Act, introduced in Dec. 2023, proposes to prohibit federal contracting with biotechnology providers connected to foreign adversaries
- If this goes into effect, it will impact any company that does (or wants to) receive US federal government contracts (i.e., most global pharma companies), and restrict them from partnering with companies of concern, including certain Chinese CROs/CDMOs
- To understand the sentiments and reactions, L.E.K. conducted a proprietary survey among global life sciences companies
- At the time of publication of this report, the US BIOSECURE Act had not been passed

L.E.K. Global Survey on Impact of the US BIOSECURE Act Respondent Mix (June 2024)

Percentage of respondents



Note: Total of 73 responses; CRO=contract research organization; CDMO=contract development manufacture organization Source: L.E.K. 2024 Global Survey on Impact of US BIOSECURE Act



L.E.K.'s survey was conducted after a draft of the BIOSECURE Act was approved by the House Oversight Committee; the full congressional approval and signing into law is not expected before year end

Timeline of the US BIOSECURE Act L.E.K. US BIOSECURE Act survey (May 24 to June 7, 2024) 型 Dec 20, 2023 March 13, 2024 June 12, 2024 S.3558 (Senate version) House excluded the BIOSECURE Act from WuXi AppTec ended its was introduced membership in its version of proposed amendments to Biotechnology Industry National Defense Authorization Act Organization (BIO) spending bill (FY25 NDAA)

Jan 25, 2024

H.R.7085 (House version) was introduced

May 10, 2024

New draft of House version (H.R.8333) introduced, adding the 8-year buffer time (2032 decoupling deadline) and clarification of "Contract"

Next milestone

Likely to be after November election unless Senate includes BIOSECURE Act in its version of FY25 NDAA before then

March 6, 2024

Senate version approved by the Senate Homeland Security Committee and reported to the Senate floor

May 15, 2024

May 10 House version was approved by the US House Oversight Committee 40-1; based on the clarification of "Contract," Medicare and Medicaid were explicitly excluded. Supply agreements with the Department of Veterans Affairs and Centers for Disease Control and Prevention, however, would still be covered

Source: US Congress, L.E.K. analysis



The US BIOSECURE Act may prompt pharma companies to diversify their supply chain away from China, creating more opportunities for ex-China suppliers



Decline in overseas upstream demand for Chinese suppliers

- The current bill only explicitly listed five companies (WuXi Apptec, MGI, BGI, Complete Genomics and WuXi Biologics) and their affiliates.
- International demand accounts for a large portion of revenue for these companies (e.g., WuXi Apptec derived 65% of its 2023 revenue from US). This Act could potentially result in a remarkable decrease in upstream demand for the services provided by the named companies.
- In addition, this may affect more Chinese CRO/CDMOs in the future, given the uncertainty of the final legislation (e.g., which companies would be designated as biotechnology company of concern) and a halo effect beyond the mentioned companies.



Increasing opportunities for ex-China suppliers

- Ex-China CRO/CDMOs could potentially benefit from the bill as pharmaceutical companies seek to diversify their production from the mentioned companies, or even from China.
- Contract organizations such as Evotec and Fujifilm Diosynth have reportedly been receiving increasing engagement and exploratory inquires.



Challenges to pharma supply chain resilience, biotechs impacted to a larger extent

- Seventy-nine percent of respondents to the BIO survey conducted in May 2024 reported that they have contracts or products being supported by a Chinese CDMO.
- Changing vendors could be challenging, time consuming and costly, especially considering the validation processes and regulatory approvals required.
- Both US and non-US biopharmaceutical companies have begun to explore mitigation plans and seek backup supplies.
- While established biopharmas often have more robust and resilient supply chain and manufacturing footprints, biotechs are expected to be impacted to a larger extent by a potential decoupling.



Key findings of L.E.K.'s 2024 Global Survey on Impact of the US BIOSECURE Act suggests that industry has started to take precautionary measures, but many remain keen to work with Chinese companies



Confidence in partnering with Chinese companies

- Confidence in working with Chinese companies has dropped by 30-50% for US-based life sciences companies, with CDMOs being the worst hit.
- Those outside of the US are also concerned, though much less so (20-30% decrease in confidence level).



Impact on current operations

- Twenty-six percent of the life sciences companies are looking to shift away from their current Chinese partners. Only 2%, however, have taken actual steps to unwind relationships with companies named in the US BIOSECURE Act.
- Still 11% of the life sciences companies report no impact on their partnership decisions. This might reflect the yet still uncertain nature of the Act.



Precautionary actions

- Sixty-eight percent of the life sciences companies are adjusting their actions, including increasing legal and compliance requirements, diversifying partnerships and adding background checks for existing partners.
- Few companies (13%) based in Asia (ex-China) are actively considering diversifying partnerships to other countries; however, background checks for existing partners are frequently reported (38%).

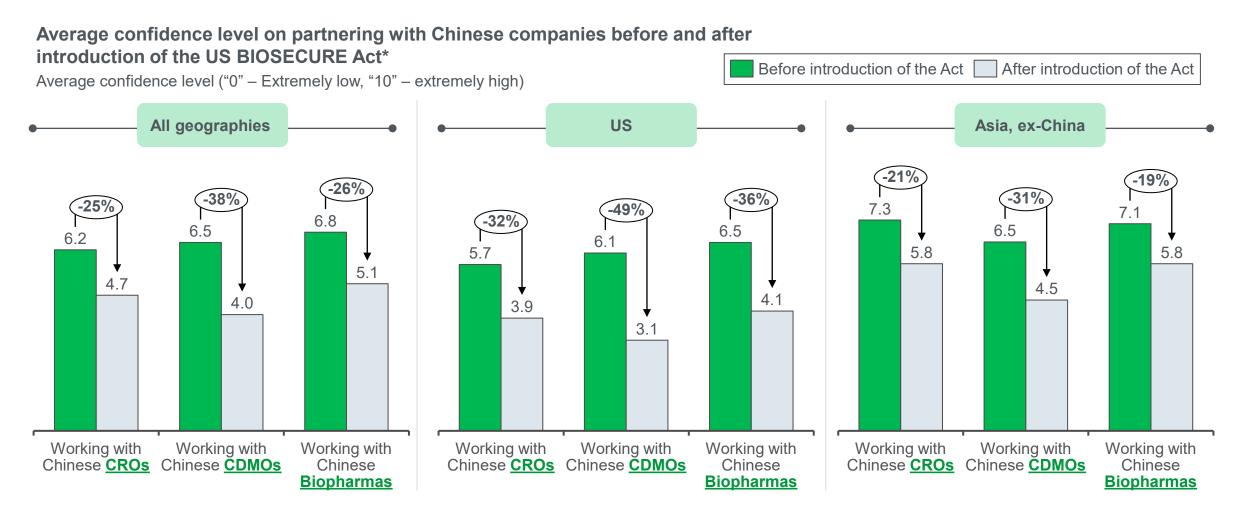


Likelihood of future partnership

- Amid the US-China biotechnology decoupling threats, the majority of the biopharmas still show high interest to partner with Chinese companies for product commercialization.
- Collaboration with Chinese service providers in clinical research, development and manufacturing are also not completely off the table, with approximately 30% of respondents considering these partnerships as likely in the next three years.



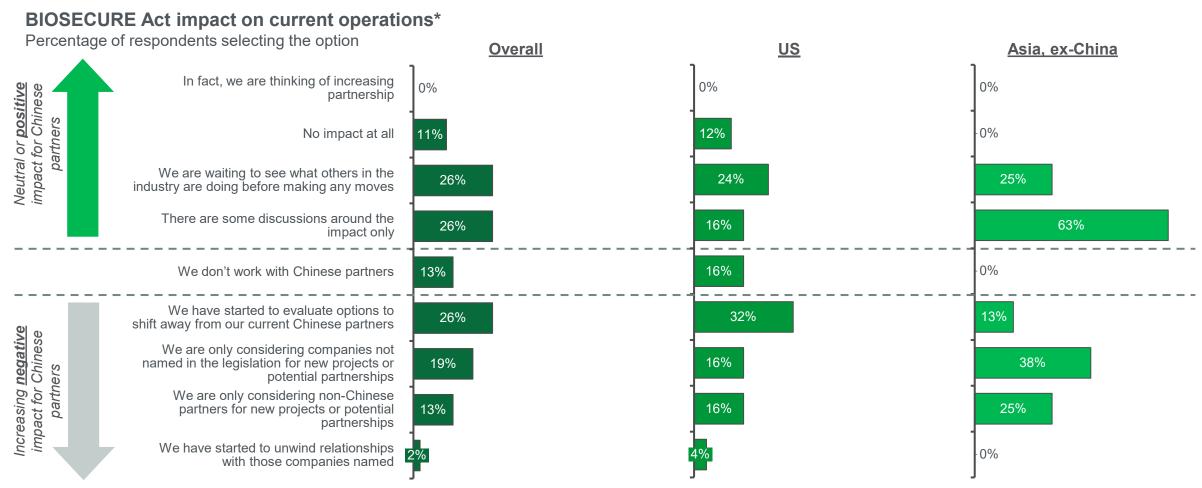
Overall confidence level on partnering with Chinese companies has decreased after the introduction of the US BIOSECURE Act, especially among US respondents



^{*}Survey question: Select, on a scale of 0 to 10, your confidence level on partnering with Chinese companies (0 is extremely low and 10 is extremely high) Source: L.E.K. 2024 Global Survey on Impact of US BIOSECURE Act



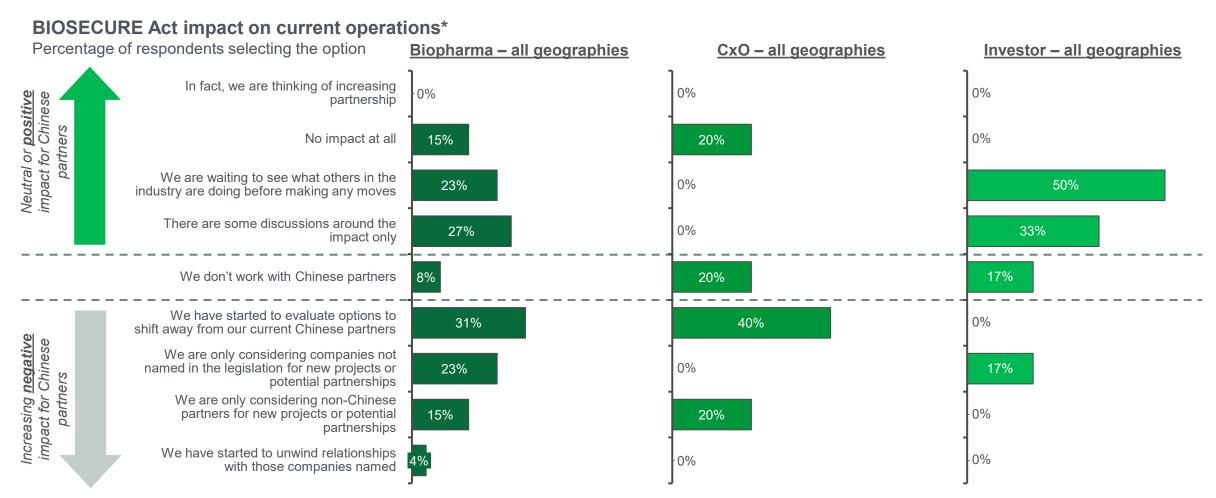
Many are reconsidering their partnerships with Chinese companies; however, only a small number have taken actual steps to unwind these relationships



^{*}Survey question: Has the BIOSECURE Act impacted your company's current operations? Select those which apply (Multi-select) Source: L.E.K. 2024 Global Survey on Impact of US BIOSECURE Act



Biopharmas and CxOs are directly impacted, while most investors adopt a 'wait and see' attitude



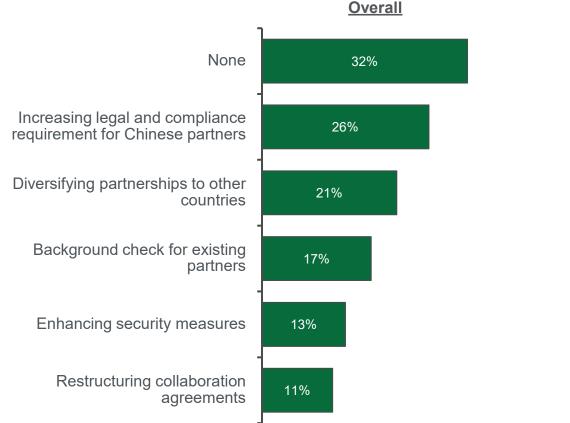
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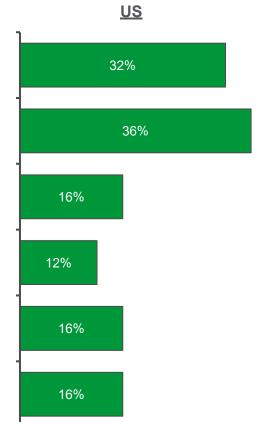


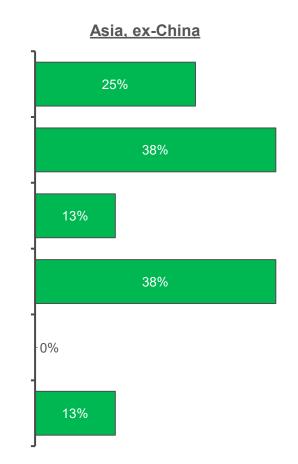
Sixty-eight percent of global life sciences companies have made strategic adjustments, including increasing legal and compliance requirements, diversifying partnerships and adding background checks

Strategic adjustments made in response to the US BIOSECURE Act*

Percentage of respondents selecting the option







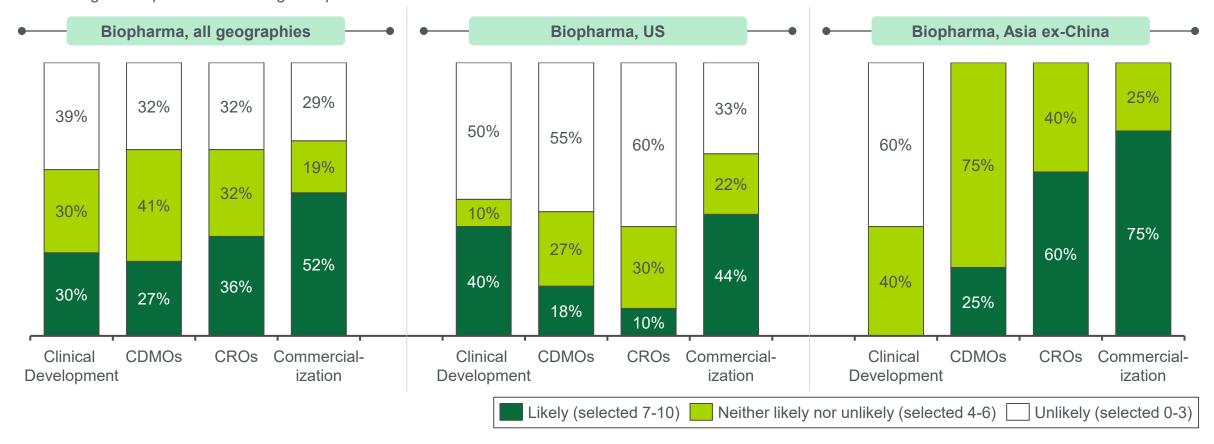


^{*}Survey question: Has your company already made any strategic adjustments in response to the US BIOSECURE Act? Select those which apply (Multi-select) Source: L.E.K. 2024 Global Survey on Impact of US BIOSECURE Act

Global biopharmas still show high interest to partner with Chinese companies for product commercialization, more so than for clinical research, development and manufacturing

Likelihood of partnering with Chinese companies in next three years after the US BIOSECURE Act *

Percentage of respondents selecting the option



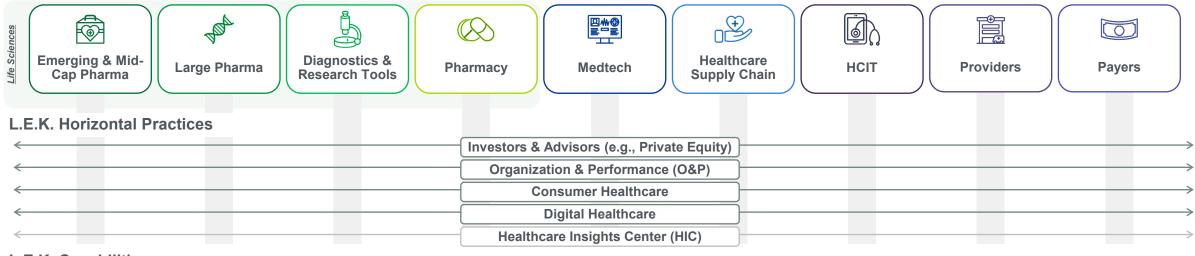
^{*}Survey question: Select, on a scale of 0 to 10, your likelihood of partnering with Chinese companies (0 is extremely low and 10 is extremely high) Source: L.E.K. 2024 Global Survey on Impact of US BIOSECURE Act



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L.E.K. Vertical Practices



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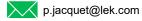
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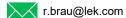
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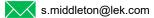
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