

# China Healthcare

## Conference takeaways: discussion with US healthcare analyst on Biosecure Act Bill

Industry Overview

On 2<sup>nd</sup> Feb, we hosted a conference “Discussion on Biosecure Bill & its implication on China CRO/CDMOs”, with our US healthcare policy analyst based in Washington DC, Andrew Bressler, CFA. He shared his views on the Biosecure Act Bill (the Bill) and answered questions we received during the call. Bressler is not a fundamental analyst covering China healthcare industry. This takeaway is based on above conference call.

### Background: US Legislation to Prohibit Contracting with Certain Biotechnology Providers

Since early Dec 2023, several bills have been introduced to prohibit contracting with certain China affiliated biotechnology providers, and specifically focused on protecting genetic and DNA data of Americans. In December, Senate Homeland Security and Government Affairs Committee Chairman Gary Peters (D-MI) introduced his legislation (S. 3558), and more recently on January 25, 2024 Congressman Mike Gallagher (R-WI), Chairman of the House Select Committee on the Chinese Communist Party, introduced a similar bill (HR 7085), titled the BIOSECURE Act. Over the last few years, there has been an effort from the Biden administration to strengthen several sectors including biotech and bio-manufacturing industry in the US, where the competitive edge of the US has narrowed with other growing economies including China. This most recent legislation has bipartisan support in both the House and Senate, and similar provisions were considered for inclusion in the National Defense Authorization Act (NDAA) that became law in December, but did not make it into the final bill that was passed in Congress, leaving the issue to be held over into this year.

The proposed legislation would prohibit US government contracting for biotechnology equipment or services provided by a company of concern; or enter into a contract with any entity that uses biotechnology or services produced or provided by a company of concern. The Bill calls for implementation guidance to be issued 180 days after enactment, and the contracting prohibitions would take effect 60 days after that for the named biotechnology companies of concern, that include: BGI, MGA, Complete Genomics, Wuxi Aptec, and any subsidiary, parent affiliate, or successor of such entities.

### Key takeaway from the Q&A sessions

**Process for the Bill to become law:** Typically, bills are introduced and referred to the relevant Committees to be amended, and move forward to a potential vote on the floor of the House or Senate. We note that for a bill to become law, both the House and Senate must agree and vote on the same version of the Bill before it is put before the President to sign into law. For context, in 2023, only 27 bills out of more than 10,000 became law.

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**David Li** >>  
Research Analyst  
Merrill Lynch (Hong Kong)  
+852 3508 4531  
[davidbo.li@bofa.com](mailto:davidbo.li@bofa.com)

**Winnie Wu** >>  
Research Analyst  
Merrill Lynch (Hong Kong)  
[winnie.wu@bofa.com](mailto:winnie.wu@bofa.com)

**Sandra Sun** >>  
Research Analyst  
Merrill Lynch (Hong Kong)  
[sandra.sun@bofa.com](mailto:sandra.sun@bofa.com)

**Ethan Cui** >>  
Research Analyst  
Merrill Lynch (Hong Kong)  
[ethan.cui@bofa.com](mailto:ethan.cui@bofa.com)

**Changyang Ji** >>  
Research Analyst  
Merrill Lynch (Hong Kong)  
[changyang.ji@bofa.com](mailto:changyang.ji@bofa.com)

NDAA: National Defense  
Authorization Act

HSGA: Homeland Security and  
Governmental Affairs

NIH: National Institutes of Health

[China Healthcare: BIOSECURE Act  
Bill proposed by US 26 January 2024](#)

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**Recent action on the Bill:** On January 31, the Senate Homeland Security and Governmental Affairs Committee held a markup to discuss the legislation, but a Committee vote on the Bill was delayed as members requested additional time to consider amendments to the Bill. With the support from the Democratic Chairman of the Committee (Senator Peters), as well as five other Republican members of the Committee, the Bill is likely to pass with bipartisan support, in Mr. Bressler's view.

**Next steps for the Bill:** If the Bill is passed out of the Senate HSGA committee, it could also be taken up in Committee in the House, or it could be attached to a larger bill, which, in Mr. Bressler's view, is the more likely path. It could happen in the next few months, but there are currently only a few potential bills that could serve as a possible vehicle. In addition, the year-end NDAA could again be a potential candidate to include the Bill.

## Summary of the Q&A session

### Q: What is the process for this Bill to become a law? How long does it take?

A: Mr. Bressler stated that, typically, when members of Congress introduced a piece of legislation, it takes a long time to go through the committee process. To introduce a bill, one needs to round up as many cosponsors as possible, and it potentially gets referred to the relevant committee who will review and potentially amend the bill in committee. The bill then would need to move to both the House and Senate floor for a vote. However, any differences between the House and Senate versions of the bill must be worked out before a final vote on the legislation in both the House and Senate. After passing both the House and Senate, the bill then goes to the President to sign into law, or veto the bill. The process could take time, ranging from 3-9 months or more to move a bill through the Congress. For context, only 27 bills were passed out of more than 10,000 pieces of proposed legislation last year.

It is noted that provisions similar to the Biosecure Act Bill were close to being included in the National Defense Authorization Act last December. However, negotiations between the House and Senate, were unable to find agreement to include the provisions in the final NDAA bill. However, as noted, in the more recent press release from the sponsors of the Bill on January 25, there is now bipartisan agreement among key members of the House and Senate, including Senator Peters (D-MI), and Congressman Gallagher, along with Congressman Raj Krshnamoorthi (D-IL) the Democratic ranking member of the Select Committee on China. The Bill now has bipartisan support in both the House and the Senate and is gaining momentum.

The proposed Bill came before the Senate Homeland Security and Government Affairs Committee on 31 Jan, but it was not voted upon as members, including ranking member Rand Paul (R-KY), had a set of amendments that they wanted to discuss. The Bill is still before the Committee, and Chairman Peters stated he plans to bring the Bill back up for a vote quickly. Given the Bill now has support from five Republican members of Committee, as well as Chairman Peters, it is likely the Bill will pass out of the Committee once it comes back for a vote.

Action on the legislation in the House is unclear, as it has yet to move in Committee. We note that if there is agreement from House and Senate leadership the Bill could be attached to other legislation that may be moving through Congress separately. Timing of this is unclear, but could happen in the next several months, or the legislation could once again be attached to the National Defense Authorization Act (NDAA) that typically moves forward at the end of the year.

### Q: What the likelihood the Bill gets passed?

A: Mr. Bressler shared that the likelihood is fairly good that the Bill moves forward out of the Committee, in his view. In Dec 2023, there appeared to be some differences in legislation that Senator Peters had introduced, however, now he is on board with the bipartisan, bicameral version of the Bill which has added momentum to getting the Bill through Committee. There are many ways the Bill could still stall in Congress, as there could be additional amendments, or lobbying to revise or delay the Bill. We note that the affected companies will likely lobby to modify or delay the Bill as well. The companies may lobby Congress to make the case that the Bill is misinformed regarding affiliations between the targeted companies and the Chinese government; as well as limitations on the risk of genetic data or information flowing back to the Chinese government. In addition, there may be concern that the legislation, if passed, would limit competition. However, Mr Bressler believes that there is strong support for the legislation, specifically to ensure that any genetic or clinical data cannot be utilized by the Chinese government. The fact that this is an election year also comes into play, as there is bipartisan focus on China. However, in an election year, there also fewer opportunities to move legislation. Overall, in Mr. Bressler's view, it has a decent likelihood of passing Congress, but more likely would need to be attached to a larger bill.

**Q: Is the Bill limited to government contracts or every single US company?**

A: Mr. Bressler shared that the Bill would prohibit any US government agencies from entering into a contract with any of these named companies, and any company that gets government funding can't contract with these named companies. This would likely include academic medical centers that receive NIH funding or grants. However, it is not clear if the Bill would extend to healthcare providers that accept Medicare or Medicaid.

Mr. Bressler believed that the Bill does not seek to target the drug manufacturer outside the US. Rather, it focuses on how certain data collected in the US is handled, particularly, genetic data and information. Thus, it should have less effect on the development of the drug as long as drug manufacturers are not using outsourcing services provided by the listed companies. However, the Bill includes provisions that would allow the government to add additional companies of concern to the list in the future.

**Q. Any measures these companies can take to be removed from the Bill?  
Including change of the management team or other ways to avoid being listed?**

A. Mr. Bressler noted that the companies could seek to clarify their ownership or operations to members of Congress to make clear that do not capture or share any genetic data or information with the Chinese government. He mentioned each of the companies who are involved could try to push back and make arguments that there is no data flowing back to the Chinese government, but these arguments may be difficult to prove. Therefore, it may be challenging to get their names removed. On the other hand, for companies not listed in the Bill, preparing supportive information in advance may ensure that they are not included in the future.

We would like to express our special thanks to Andrew Bressler, who shared his professional views on our conference call.

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