BIOSECURE Act: Companies turn to US manufacturers

By **Abigail Beaney** | October 15, 2024

During Covid-19, US companies had to find onshore manufacturing. Experts believe this may also be an answer to the BIOSECURE Act.

Despite many companies believing that a great deal of manufacturing will go to India, others believe that the US will likely see a big uptick.

The BIOSECURE Act's impact is likely to benefit US-based manufacturing facilities as companies try to avoid falling foul of potential legal issues.

The act, which seeks to prohibit federal agencies from contracting with or providing funding to any company working with a "biotechnology company of concern", was passed by the House of Representatives in September, meaning it now only needs to get Senate approval to be made law.

The timeline for this is difficult to judge as the Senate is currently focused on avoiding a government shutdown ahead of the November presidential election. The House-agreed version of the act has not been included in the House Rules Committee's list of floor amendments to the lower chamber's National Defense Authorization Act (NDAA).

"It still has a good probability of passing even though it's not included in the Senate's version of the NDAA," said John Strom, special counsel in the Public Policy and Government Relations Practice Group at law firm Foley and Lardner.

Several major names in the contract development and manufacturing organisation (CDMO) field have been named in the bill including WuXi AppTec.

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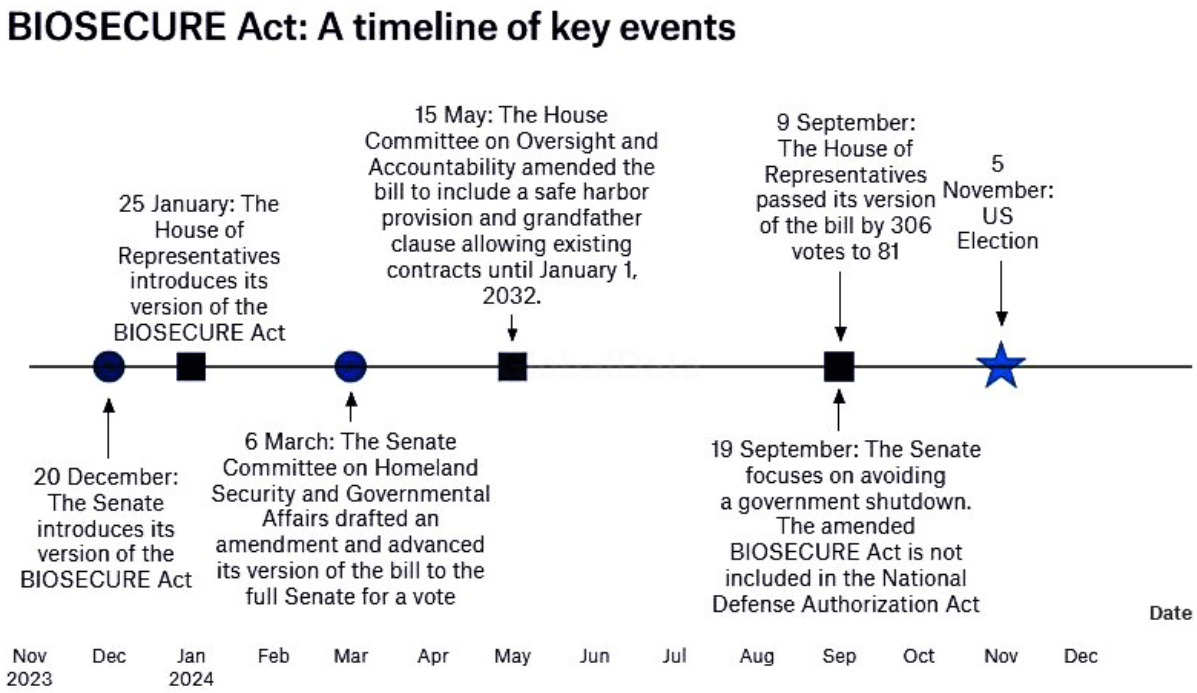
Companies moving away from these CDMOs will not want to be hit again should more companies and countries be added to the bill. Despite previous reports touting India as the next big manufacturing hub, some experts believe that US companies may source onshore manufacturing solutions to avoid any potential for a second sting.



Companies share fears

Pharma companies are already publicly sharing their fears about the potential impact on their clinical studies, despite it not having yet been officially passed by the Senate.

In financial reports, Cabaletta Bio shared concerns about its Phase I/II RESETTM trials for CABA-201, Phase I clinical trial of DSG3-CAART, and the Phase I clinical trial of MuSK-CAART, or the MusCAARTesTM trial, all of which are being operated in collaboration with the University of Pennsylvania and WuXi AppTec.

"If the University of Pennsylvania or WuXi's manufacturing capacity is reduced or otherwise delayed or limited, including due to legislative action, this could adversely impact enrolment in our trials," the financial report reads.

Arcus Biosciences also shared concerns as WuXi is the sole manufacturer of its investigational candidates zimberelimab and domvanalimab. "If WuXi Biologics, or any other manufacturer that we rely on, is unable or unwilling to provide the quantity of material we require, there is no guarantee that the reserve of our investigational products that we currently have will be sufficient for our future clinical development plans. If our reserves are depleted and we are unable to establish a reliable source of supply, our development efforts, and if approved, commercial activities could be delayed or impaired," the company said in an SEC filing.

Change will not happen overnight, experts say, adding that the clause allowing current contracts to continue until 1 January 2032, will act as a saving grace for small and medium-sized biotechs.

Sibaji Biswas
ED & CFO, Syngene International

It has been heavily reported that India is likely going to become the next big manufacturing hub, with Sibaji Biswas, executive director and chief financial officer at India-based CDMO Syngene saying the company has already noticed an uptick in interest for its services, despite the fact the act has not yet passed.

"Partners – both big pharma and biotech – want to work with fewer, but more capable CDMOs so that they can simultaneously advance more targets at the same time," Biswas says. "There's a move away from the old idea of outsourcing to a partnership approach. So, there's this ongoing shift towards building deeper relationships with clients, it's much more interactive and iterative now."

Tim Roberts, chief commercial officer at PCI Pharma Services, a US-based CDMO, says that lessons from the Covid-19 pandemic, which forced companies to shift to on-shore manufacturing, are leading more companies to choose US CDMOs.

"We saw these challenges during Covid-19 in manufacturing, importing, and exporting. At that time, to manufacture in Asia, and to bring those to the US was a tough supply chain challenge," Roberts says.

"This set forth an initiative to use onshore manufacturing, not just of pharmaceuticals, but of everything. I think the BIOSECURE Act takes that thinking one step further. There is a geopolitical challenge around it, but because of that, we continue to see that push for onshoring and as a result, manufacturing elements in North America are growing," Roberts adds.

CEO of US-based CDMO BioCentriq, Syed Husain, agrees, adding that if companies are focussing on drug launches in the US, any developmental contracts should also be focussed in the US.

"An act like this doubles down on the fact that US-based manufacturing first and foremost should be everyone's focus because that's where also you're going to launch," Husain explains.

Ali Pashazadeh
CEO, Treehill Partners.

Onshore manufacturing could be pricey for smaller enterprises

"Manufacturing globally must hit a certain standard so whether it's manufactured by Chinese, Japanese, Indian, US or European entities, the standard they need to hit will be the same. The standard deviation cost when you are going for that high-quality product is not as high as it is when it is a small manufacturer in a non-US or non-European region," says Pashazadeh.

However, Roberts adds that the government will need to support smaller companies financially if this decision is being pushed upon them to ensure that their capabilities are not hindered.

"There will need to be governmental support for onshoring, whether that be tax breaks or something similar. I think however that onshore manufacturing adds value to the company and will increase its market cap because they are seen as having a much more secure and viable supply chain," Roberts explains.

Husain adds that cost should not be a consideration for whether companies support the BIOSECURE Act or not.

"In cell therapy manufacturing, looking at China versus the US, whether it will cost more is not clear yet. In more established modalities, there is a clear cost difference because of the cost of labour and more. In the short term, cost is not the main thing companies should focus on as a reason to support or not support the act," Husain explains.

The companies most likely to be hit by financial troubles due to the act are those developing drugs for rare diseases. Many rare disease companies tend to be smaller or medium-sized biotechs with limited funding, mostly from investors as opposed to being on the stock market. As a result, they depend on government grants and priority review vouchers, meaning they will have a difficult decision to make, says Strom. "Do they take the grants and not work with these companies, or do they decline the grants and retain the ability to work with them?"

John Strom
Special Counsel in the Public Policy and Government Relations Practice Group at Foley and Lardner

Company action

Despite the act being introduced nearly 12 months ago, Pashazadeh said it has only been in the past couple of months that it has become a talking point with biotechs. He believes the transition will take time, but companies should still put preventative measures in place.

Syed Husain
CEO, BioCentriq

"I would see things going smooth for now. Board members over the next six to 12 months are likely going to set up a backup plan just in case there is a change in the act," says Pashazadeh.

Strom agrees that companies should protect themselves, especially those seeking contracts with Chinese CDMOs, by including a clause allowing them to terminate the contract should the act broaden.

"It would be a very prudent measure to include because the process for listing biotechnology companies of concern can come extremely quickly. Companies are not even required to be told specifically why they're being designated as a risk," Strom says.

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