

23 Sep 2024 | Data

BIOSECURE Act: Pfizer To Lilly - Where Are The Likely Sourcing Gaps?

by Vibha Ravi

Lilly's Mounjaro to Pfizer's Paxlovid, the WuXi group has been part of pharma majors' sourcing chain. How big is the hole clients are to fill when the proposed BIOSECURE Act comes into effect? Here's a *Scrip* infographic using *Evaluate Pharma* data.

As the BIOSECURE Act gets closer to reality, *Scrip* looks at a couple of products where it could create gaps for US pharma majors and opportunities for other contract development and manufacturing organizations (CDMOs) as business moves away from *WuXi AppTec Inc.* and *WuXi Biologics*.

Way before the bill for the BIOSECURE Act cleared the US House of Representatives in September, *Scrip* took a detailed look at the possibility of sourcing shifts. (*see sidebar below*)

Here's a follow-up with relevant details curated from an *Evaluate Pharma* dataset on the CDMO industry, which incorporates information from publicly available sources, and presented in an infographic.

It's no secret that some of the largest pharma firms are based in the US, which also happens to have the highest per capita pharmaceutical spending.

Juxtaposing graphics on the count of facilities (R&D centers, manufacturing units) and CDMO headquarters in the US

Proposed US BIOSECURE Act - Do Lonza, Other CDMOs Gain And How Soon?

By Vibha Ravi

27 Mar 2024

Concerns over the impact of the proposed US BIOSECURE Act on the CRO and CDMO segments linger despite proponent Mike Gallagher's plan to leave Congress soon.



with global CDMO revenues shows just why the proposed Act has potential to cause a significant shift in the industry landscape if its execution matches intent.

The proposed BIOSECURE Act names Wuxi Biologics, Wuxi AppTec, **BGI**, MGI and Complete Genomics Inc. as biotechnology companies of concern without regard to other criteria listed in the bill for a company to qualify as such. Which global manufacturers could gain, what determines a shift away from Chinese companies and how imminent is this? Scrip brings insights from industry feedback and other sources.

Read the full article here

WuXi STA, WuXi XDC, WuXi Advance Therapies and WuXi Vaccines are other firms of the same group, but they have not been named so far.

About one-third of the total 2023 revenues of the global top 10 CDMOs went to Wuxi Biologics, Wuxi AppTec and WuXi STA, described as "an integral part of WuXi AppTec", proving without doubt that these three are among the titans of the industry.

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The BIOSECURE Act now provides for time before 2032 to shift business away from the named Chinese CDMOs, but the clock is ticking.

Analysts estimate a few of the non-WuXi group firms from China, apart from Indian CDMOs, are likely to benefit from an expected shift in sourcing given the imperative need to keep development and manufacturing costs in check. For them, a growing focus on drug pricing in the US, particularly post the Inflation Reduction Act, is a definite tailwind.

However, clientele of the WuXi group of companies includes Chinese and Indian names too, implying that not just the language of the final BIOSECURE Act, but also its implementation regarding 'Companies Of Concern' will have significant bearing on the extent of the impact.

It is not clear if and which other CDMOs might be caught in the BIOSECURE Act net in the future, but here are some of the other big fish in the Chinese ocean.



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For brevity, a limited number of products where sourcing gaps could arise are shown above, based on company disclosures and other publicly available information, but *Evaluate* data show many more products being developed or manufactured by the WuXi group or firms linked to it.

The group has a finger in several pies, including in biotechs on the cusp of making breakthrough discoveries. According to Bernstein, emerging biopharma-sponsored pipelines increased their overall CDMO industry share to 64% in 2022, compared to 50% five years back in 2017.

Thus, opportunities could be created for non-WuXi group CDMOs to develop and make other drugs as well, but this assessment surely gives an idea of what is in store as the bill progresses to the Senate. As part of ongoing curation and maintenance, these mappings will continue to be expanded and updated.

Be prepared, change is afoot!