Bourne Meetings at BIO 2024

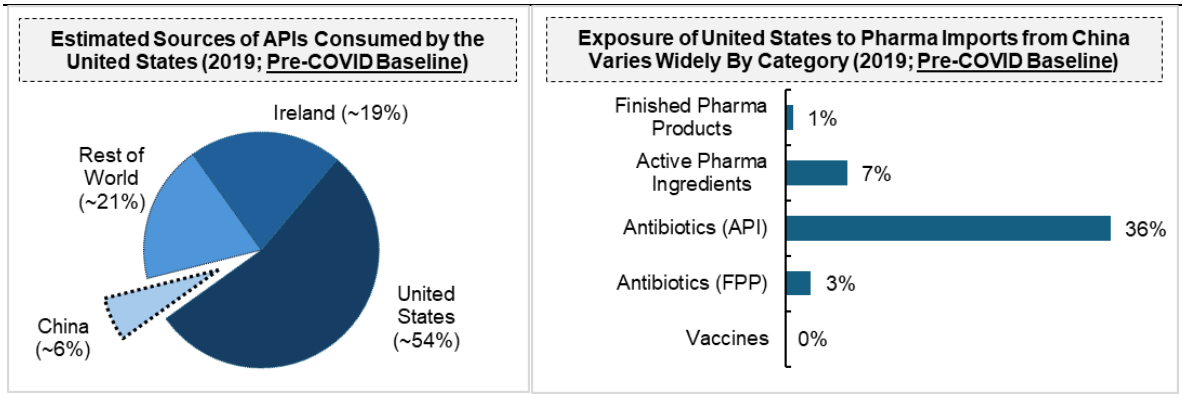
Hopes and Concerns Related to the Pending "BIOSECURE Act"

In our view, **the pending BIOSECURE Act could create significant near-term volatility to the global life sciences industry** by pressuring biopharma manufacturing and services towards "politically safe" geographies (such as the United States or Europe). The most recent amendment to the legislation in mid-May was loosened to include an 8-year grandfathering provision for existing contracts. Even still, we would argue that life sciences companies need to consider their supply and service relationships *now* in order to avoid potential future compliance risks with the U.S. government (and possible retaliatory responses by the Chinese government). This has been highlighted by recent survey data released by the Biotechnology Innovation Organization (BIO) and our meetings at the BIO 2024 Conference in San Diego this week. In fact, we think anticipation of this legislation is *already* putting a premium on U.S.-based biopharma manufacturing and storage capacity -- as well as on domestic pharma services providers.

We see the current iteration of the BIOSECURE Act as severely limiting the ability of Chinese biopharma and life sciences companies from doing business in the United States. Specifically, the draft legislation would prohibit the U.S. government from doing business with any "biotechnology company of concern" (i.e., any company with ties to any country identified as a "foreign adversary"). The legislation further prevents private companies that contract with or receive funding from the U.S. government from also having contracts with such companies. A "biotechnology company of concern," in turn, is broadly defined as "any entity" that is "to any extent" involved in the manufacturing, distribution, provision, or procurement of a "biotechnology equipment or service." In essence, the BIOSECURE Act would put life sciences companies in the position of having to choose between ever doing business with the U.S. government or doing business with companies associated with countries deemed as "foreign adversaries" of the U.S. government.

Importantly, even after passage, life sciences companies would need to consider that the BIOSECURE Act could evolve since the bill gives **significant ongoing discretionary power to the U.S. Director of the Office of Management and Budget (the OMB).** U.S. foreign policy priorities could change, particularly only months ahead of a Presidential election. Currently, the legislation points to China, Russia, Iran, and North Korea as "foreign adversaries" -- with specific references to companies such as WuXi AppTec, WuXi Bio, BGI Group, MGI, and Complete Genomics. Doing business with a "biotechnology company of concern" is further broadly defined as procuring equipment, services, software, or consulting associated with the "research, development, production, analysis, detection, or provision of information related to biological materials."

Figure 1: Estimates of the Exposure of U.S. Pharma to China Vary Depending on the Source

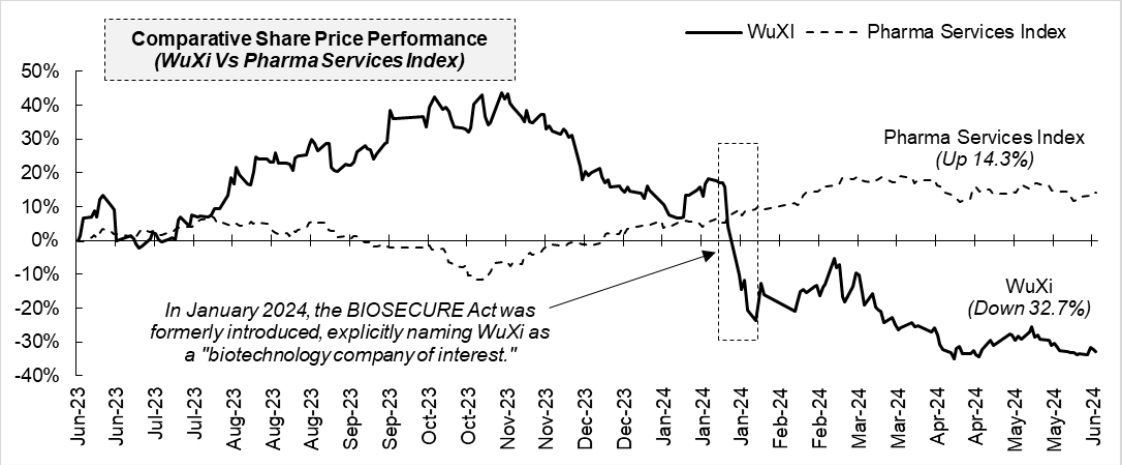


Note: The data above accounts for all three ways APIs enter the supply chain for U.S. consumed medicines: API imports, domestic production of APIs, and APIs used in imports of finished pharmaceutical products.
Source: Avalere Health, U.S. Census, and Bourne Partners

The passage of the BIOSECURE Act would fall in the footsteps of increasingly aggressive national security actions taken by the Biden administration, particularly towards China. For example, the Committee on Foreign Investment in the United States (CFIUS) has ramped up its activities across multiple industries. In 2022, President Biden issued an Executive Order directing the CFIUS to consider the risks a transaction poses to U.S. technological leadership in certain key sectors, including biotechnology and biomanufacturing. Later, in August 2023, the U.S. government announced the creation of a new outbound investment program that requires notification of certain Chinese investments by U.S. persons in semiconductors, microelectronics,

information technologies, and artificial intelligence. While this outbound investment program does not explicitly address the life sciences, it is possible (and maybe even likely) that this program too could be expanded to include a broader range of industries.

Figure 2: WuXi Share Price Significantly Negatively Impacted by the Introduction of the BIOSECURE Act



Note: Market values are as of the close of business June 5, 2024. The "Pharma Services Index" consists of a variety of companies selling into the biopharma space such as Avid Bioservices (CDMO), Charles River Laboratories (CRL), ICON (ICLR), IQVIA Holdings (IQV), Medpace (MEDP), and Veeva Systems (VEEV).
Source: S&P Capital IQ and Bourne Partners

Looking ahead, **the full impact of the BIOSECURE Act is unclear, although we think most investors we talk to view it as "net positive" for U.S. CDMOs, CROs, and other services vendors.** Official collection of the volume and dollar value of production per country would be necessary to determine the exact impact of China on the U.S. (and global) life sciences industry with certainty – and this data is not available. Also, it is impossible to calculate the derivative and downstream impacts of the legislation with respect to things like supply shortages of active pharmaceutical ingredients (APIs) and/or access to critical equipment and supplies. Many U.S. life sciences companies use suppliers and service providers in countries like China to reduce costs and take advantage of relatively favorable regulatory environments. For instance, according to recent survey data from the Biotechnology Innovation Organization (BIO), 79% of U.S. biopharma companies report having at least one contract or product agreement with a Chinese owned manufacturer (including 9% who reported having more than 25 such contracts). Anecdotally we understand that many U.S. companies have already been initiating efforts to diversify their supply and service vendors since the COVID-19 pandemic. However, this has more recently been offset by a historically strong U.S. dollar. Based on various estimates, we would ballpark that as much as ~10% of today's pharma supply chain likely originates in China.

While the full impact of the BIOSECURE Act is unknown, the timing of the impact would be almost immediate, in our view. Although the most recent draft of the legislation "grandfathers" existing contracts through January 2032, companies would need to immediately start re-evaluating their supplier and service relationships given the long lead times needed for planning and contracting. Data from the same BIO survey referenced above suggests that U.S. biopharma companies would require a lead time of six months to six years to change manufacturing relationships. This is due to the need to conduct test runs and validation and the need for regulatory approvals of new suppliers. Similarly, drug development can take as much as a decade and there are upwards of 60 drugs in Phase I-III clinical development that currently rely on a Chinese CDMO, according to the GlobalData Pharma Intelligence Center Deals Database. In fact, more than 45 U.S. biopharma companies have a contract service agreement, licensing agreement, or partnership deal with the companies explicitly named in the BIOSECURE Act. Finally, since the bill's introduction in January, multiple U.S. biopharma companies, including Merck, Gilead Sciences, and Vertex Pharmaceuticals, have cited risks of increased costs and delays in clinical trials related to the BIOSECURE Act in their financial filing.

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