

# Debevoise National Security and Life Sciences Update: The BIOSECURE Act

May 22, 2024

On May 15, 2024, the U.S. House Committee for Oversight and Accountability (the “Committee”) voted 40-1 to approve the BIOSECURE Act (the “Act”). The Act aims to use the purchasing power of the U.S. federal government to encourage life sciences companies to sever ties with certain Chinese “biotechnology companies of concern” and to monitor their supply chains for any biotechnology products or services produced or provided by such entities. As we previously wrote, in the name of U.S. national security, Congress has increased scrutiny over supply chains involving countries designated as foreign adversaries.<sup>1</sup> The overwhelming support for the Act is the latest manifestation of this trend, which follows similar bipartisan approval from the Senate Committee on Homeland Security and Governmental Affairs on March 6, 2024.

If enacted, the BIOSECURE Act would have a significant impact on U.S. companies with supply chains that have a nexus to any biotechnology company of concern. This Debevoise In Depth addresses the implications of the Act for life sciences companies and other affected parties, and offers advice on how they can prepare for its potential enactment.

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## The BIOSECURE Act

The BIOSECURE Act is the latest of several efforts by U.S. Congress to secure the nation’s supply chain against alleged national security risks posed by the Chinese Communist Party (the “CCP”). According to its co-sponsors, the Act is intended to (i) prevent the CCP from accessing genomic data that Chinese biotechnology companies collect; (ii) protect pharmaceutical supply chains from exploitation; and (iii) prevent Chinese biotechnology companies from “harvesting” Americans’ genetic information.<sup>2</sup>

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<sup>1</sup> See *Debevoise National Security Update: Supply Chain Security in 2024*, debevoise.com (March 11, 2024), available at <https://www.debevoise.com/insights/publications/2024/03/debevoise-national-security-update-supply-chain>.

<sup>2</sup> See Moolenaar, Krishnamoorthi, Wenstrup Introduce Bipartisan BIOSECURE Act to Safeguard American Patients and Tax Dollars from Biotechnology Firms in China, [selectcommitteeontheccp.house.gov](https://selectcommitteeontheccp.house.gov) (May 10, 2024),

The Act, as approved by the Committee, would prohibit U.S. executive branch agencies from procuring or obtaining any biotechnology equipment or service produced or provided by a “biotechnology company of concern,” or from entering into, extending or renewing a contract with any entity if biotechnology equipment or services of a “biotechnology company of concern” would be used in the performance of that contract.<sup>3</sup> The Act also prohibits U.S. executive branch agencies from providing loans or grants to, and recipients from expending those funds on, a “biotechnology company of concern” or entities that use biotechnology equipment or services from a “biotechnology company of concern.”<sup>4</sup>

The Act defines a “biotechnology company of concern” to include:

- Chinese companies BGI, MGI, Complete Genomics, WuXi Apptec and Wuxi Biologics,<sup>5</sup> which, according to the Act’s sponsors, collect, test and store genomic data of Americans;<sup>6</sup>
- Additional entities that the U.S. Office of Management and Budget (“OMB”) will identify within one year of the Act’s enactment that, among other things, are subject to the jurisdiction of a foreign adversary’s government, are involved with biotechnology equipment or services, and pose a threat to national security;<sup>7</sup> and
- Any of the subsidiaries, parents, affiliates or successors of a designated entity that are also subject to the jurisdiction of a foreign adversary.<sup>8</sup>

The Act contains measures intended to alleviate the risk of supply chain disruptions in the pharmaceutical industry. *First*, it grandfathers until 2032 contracts with biotechnology companies of concern executed prior to the Act’s effective date.<sup>9</sup> *Second*, the Act contains a safe harbor provision that exempts “any biotechnology equipment or services that were formerly, but are no longer, produced or provided by biotechnology companies of concern.”<sup>10</sup> *Third*, it authorizes the heads of agencies to waive the prohibition on a case-by-case basis if they receive approval from the Director of OMB to

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available at <https://selectcommitteeontheccp.house.gov/media/press-releases/moolenaar-krishnamoorthi-wenstrup-introduce-bipartisan-biosecure-act-safeguard>.

<sup>3</sup> See H.R. 8333, *Amendment in the Nature of a Substitute to H.R. 8333 Offered by Mr. Comer of Kentucky*, § 2(a), available at <https://oversight.house.gov/wp-content/uploads/2024/05/BILLS-118-HR8333-C001108-Amdt-4.pdf> (“HR 8333”).

<sup>4</sup> *Id.* § 2(b).

<sup>5</sup> *Id.* § 2(f)(2)(A).

<sup>6</sup> See *supra* n. 2.

<sup>7</sup> See HR 8333 § 2(f)(2)(B).

<sup>8</sup> See *id.* § 2(f)(2)(C).

<sup>9</sup> See *id.* § 2(c)(3)(A).

<sup>10</sup> *Id.* § 2(c)(3)(C).

provide health care services overseas.<sup>11</sup> And finally, the Act defines “contract” in a way that excludes Medicaid national drug rebate agreements and Medicare Part D manufacturer discount agreements.<sup>12</sup>

The Act has been voted out of committee in both the U.S. House of Representatives and the U.S. Senate, and a final vote may be forthcoming. There are discrepancies between the House and Senate versions of the Act. For example, the Senate version does not include the safe harbor, includes an uncapped grandfathering clause and excludes Wuxi Biologics as a “biotechnology company of concern.”<sup>13</sup> These differences would need to be reconciled before Congress approves the final bill.

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## Key Takeaways and Mitigation Measures

If enacted, the BIOSECURE Act could have a significant impact on, and create substantial disruptions for, U.S. companies with supply chains that have a nexus to any biotechnology company of concern. Although several of the Act’s provisions are intended to blunt the disruption, the Act is designed to incentivize U.S. companies to diversify away from using Chinese-based biotechnology goods and services and to replace them with alternative suppliers and service providers.

That could lead to significant changes in commercial contracting and supply chain monitoring in the pharmaceutical and biotechnology industries. U.S. pharmaceutical and biotechnology companies often hire Chinese contract development and manufacturing organizations (“CDMOs”) for services including product manufacturing, development, formulation, packaging and distribution. Those companies may have to choose between working with “biotechnology companies of concern” or doing business with the U.S. federal government. The scale of the identified biotechnology companies of concern is significant, with some of them contracting with a significant percentage of U.S. pharmaceutical and biotechnology companies. The BIOSECURE Act therefore could put additional pressure on the resilience of pharmaceutical and biotechnology supply chains, which are already strained by ongoing drug shortages.

As we have seen with other national security regulatory regimes, such as those related to telecommunications supply chains, what begins as a prohibition on U.S. government purchases of goods or services can expand over time and effectively become a broader

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<sup>11</sup> See *id.* § 2(d).

<sup>12</sup> See *id.* § 2(k)(3).

<sup>13</sup> See S. 3558, *A Bill to Prohibit Contracting with Certain Biotechnology Providers, and For Other Purposes*, available at <https://www.congress.gov/bill/118th-congress/senate-bill/3558?q=%7B%22search%22%3A%22s+3558%22%7D&s=3&r=1>.

prohibition on U.S. companies or consumers. In addition to monitoring developments with the BIOSECURE Act, life sciences companies and other potentially affected parties can take proactive steps to mitigate their compliance risk:

- **Mapping Supply Chains.** Potentially affected companies should inventory their supply chains to identify if and how they are exposed to risks from China-based suppliers, including by conducting risk-based supply chain mapping and due diligence on Chinese suppliers to ensure they do not contain components produced by “biotechnology companies of concern.”
- **Diversifying Suppliers as Necessary.** Potentially affected companies that contract with known “biotechnology companies of concern” should weigh the risks of entering into new agreements and consider whether they should take steps to begin diversifying away from such entities. Although old contracts are likely to be grandfathered, prohibitions on new engagements with the government could take effect as soon as 120 days after the BIOSECURE Act is enacted.<sup>14</sup> Similarly, companies with plans to enter, extend or renew covered U.S. government contracts, loans or grants should consider the potential impact on agreements with biotechnology companies of concern.
- **Developing a Supply Chain Mitigation and Response Plan.** Potentially affected companies should develop a supply chain mitigation and response plans to mitigate the risk of supply chain and operational disruption should OMB identify a direct or indirect supplier as a “biotechnology company of concern.”

We will continue to monitor developments related to the BIOSECURITY Act and its potential enactment in 2024.

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Please do not hesitate to contact us with any questions.

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<sup>14</sup> The Act requires OMB to establish implementation guidance to executive agencies within 120 days of enactment. See H.R. 8333, § 2(f)(3).



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