
**UNSECURE HEALTH:
WHAT THE BIOSECURE ACT COULD MEAN
FOR THE BIOPHARMACEUTICAL INDUSTRY**

❖ Note ❖

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I. INTRODUCTION

On January 19, 2025, TikTok, a social media platform owned by Chinese company ByteDance which provides short form video content to over 170 million users, shut down in the United States.¹ The bill to block TikTok was passed in April 2024 with an overwhelming majority in both the House and the Senate due to growing bipartisan fears of national security risks.² The Supreme Court upheld the TikTok ban, sharing Congress's national security concerns of TikTok's collection of data privacy.³ However, the ban lasted a mere eighteen hours.⁴ The first day of President Trump's term, his administration effectively stalled the ban and brought TikTok back to the U.S. via executive order.⁵ However, while the Trump administration appears supportive of TikTok in the U.S., the executive order only delays the ban: TikTok must eventually sever its ByteDance—and essentially Chinese—connection to maintain its presence in the United States.⁶

The TikTok ban illustrates a growing trend in American politics to sever private companies' relationships with foreign adversaries—a trend which extends to

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¹ Bobby Allyn, *Trump Signs Executive Order to Pause TikTok Ban, Provide Immunity to Tech Firms*, NPR (Jan. 20, 2025, 8:22 PM), <https://www.npr.org/2025/01/20/nx-s1-5268701/trump-executive-order-tiktok-ban>.

² Antonio Pequeño IV & Mary Whitfill Roeloffs, *TikTok Ban Timeline: TikTok Returns to U.S. App Stores—For Now*, FORBES (Feb. 14, 2025, 2:39 PM), <https://www.forbes.com/sites/antoniopequenoi/2025/02/14/tiktok-ban-timeline-tiktok-returns-to-us-app-stores-for-now/>.

³ Allyn, *supra* note 1.

⁴ *Id.*

⁵ Exec. Order No. 14166, 90 Fed. Reg. 8611 (Jan. 20, 2025).

⁶ Allyn, *supra* note 1.

biotechnology industries.⁷ On September 9, 2024, the House of Representatives passed the bipartisan bill H.R. 8333, also known as the BIOSECURE Act.⁸ The BIOSECURE Act first prohibits executive agencies from both procuring any technology or services from a biotechnology company of concern.⁹ A “biotechnology company of concern” is any company subject to a foreign adversary, i.e., any Chinese, North Korean, Iranian, or Russian company.¹⁰ The BIOSECURE Act specifically names five major Chinese biotechnology companies as companies of concern: BGI, MGI, Complete Genomics, WuXi AppTec, and WuXi Biologics.¹¹ The BIOSECURE Act further prohibits executive agencies from entering into, or extending, any contract with an entity that “uses any equipment or services produced or provided by a biotechnology company of concern” for an executive agency contract, if the equipment or services are procured after the effective date of the bill.¹²

Like the TikTok ban, the BIOSECURE Act stems from increasing Congressional concerns that foreign-run biotechnology companies are accessing and exploiting American data, posing a risk to national security.¹³ However, many U.S. based biopharmaceutical companies have contracts with companies that could be classified as biotechnology companies of concern.¹⁴ This means that if the BIOSECURE Act is passed it will cause a major restructuring of the global biopharmaceutical industry, as American companies will have to navigate new contracts and programs without the support of international biotechnology companies.¹⁵

While there are legitimate concerns about foreign adversaries accessing U.S. health technology and data through international partnerships in biotechnology, the BIOSECURE Act will cause a major delay in the biopharmaceutical industry that may take years to recover from.¹⁶ This Note argues that the BIOSECURE Act should not be passed in Congress until revisions are made that will either grant companies more time to contract away from biotechnology companies of concern and invest in American biotechnology.

⁷ David M. McIntosh, Arthur C. Mok & Geoffrey Lin, *BIOSECURE Act Passed in the House of Representatives with a 306-81 Vote*, ROPES & GRAY (Sept. 17, 2024), <https://www.ropesgray.com/en/insights/alerts/2024/09/biosecure-act-passed-in-the-house-of-representatives-with-a-306-81-vote>.

⁸ *Id.*

⁹ BIOSECURE Act, H.R. 8333, 118th Cong. (2023–2024).

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ John Strom & Katie Kros, *BIOSECURE Act: Anticipated Movement, Key Provisions, and Likely Impact*, FOLEY & LARDNER LLP (Sept. 10, 2024), <https://www.foley.com/insights/publications/2024/09/biosecure-act-anticipated-movement-key-provisions-impact/>.

¹⁴ Jaxon Tan & Ivy Yang, *Opinion: BIOSECURE Act Threatens Already Strained U.S. Supply Chain*, BIOSPACE (Sept. 9, 2024), <https://www.biospace.com/business/opinion-biosecure-act-threatens-already-strained-u-s-supply-chain/>.

¹⁵ *Id.*

¹⁶ See *infra* Part II.

Part II of this Note will discuss the current status of the American biotechnology industry, focusing on potential and current biotechnology companies of concern,¹⁷ the history of the BIOSECURE Act and current potential planned reforms,¹⁸ as well as the U.S.'s potential investment into domestic biotechnology and biomanufacturing resources.¹⁹ Part III will analyze the impact of losing relationships with Chinese biotechnology companies, and potential problems with the prohibition of loans, grant funds, and the classification clauses of the proposed bill.²⁰ Part IV provides recommendations for how the U.S. biopharmaceutical industry should prepare for the BIOSECURE Act, emphasizing reinvestment in domestic production of biotechnology.²¹ Part IV further recommends changes in the BIOSECURE Act, such as incorporating the Senate's grandfather clause into the House's proposed BIOSECURE Act²² and limiting the scope of the BIOSECURE Act to prohibit federal funding only if the company affiliates itself with a biotechnology company of concern in performance of an executive contract.²³

II. BACKGROUND

A. The Current Status of the U.S. Biopharmaceutical Industry

When discussing “biotechnology” and “biopharmaceuticals,” it is important to first understand the meaning of these terms and how they relate to each other. Biotechnology refers to the industry concerned with using biology to make new products, as well as making use of organisms and living processes for research purposes.²⁴ Biopharmaceuticals refers to the industry concerned with making medicines and drugs, typically through using living organisms produced by biotechnology industries.²⁵ Thus, the biopharmaceutical industry is closely intertwined with biotechnology industry.²⁶ This Note is specifically concerned with the impact of the BIOSECURE Act on the biopharmaceutical industry regarding drug production and distribution. While the BIOSECURE Act specifically mentions biotechnology companies of concern, many of the BIOSECURE Act's named biotechnology companies are close partners with biopharmaceutical companies and have helped

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *See infra* Part III.

²¹ *See infra* Part IV.

²² *Id.*

²³ *Id.*

²⁴ Brinson Brothers, *Biotechnology vs Biopharma: What's The Difference?* BIOTECH HEALTH (Aug. 1, 2020), <https://biotechhealth.com/biotech-vs-pharma/>.

²⁵ *Id.*

²⁶ *Id.*

develop several drugs in the United States.²⁷ Thus, the BIOSECURE Act is also pertinent to the biopharmaceutical industry.

Currently, the U.S. is the leading contributor to the biopharmaceutical industry, holding forty-four percent of the pharmaceutical market share worldwide in 2023.²⁸ Though the U.S. is currently the leading force in the biopharmaceutical market, Asia's presence in the biopharmaceutical industry is expected to grow quickly in the next ten years, especially China.²⁹ This sharp growth in the Chinese biopharmaceutical industry is due to its increasing participation in the global market, investment into Research & Development ("R&D") and strong government support.³⁰ Additionally, many of the top biopharmaceutical companies³¹ invest in health services in emerging companies in countries considered foreign adversaries.³² The U.S. biopharmaceutical industry has a tradition of international collaboration and relies heavily on Chinese biotechnology companies.³³

B. U.S. Executive Investment into Domestic Biotechnology and Biomanufacturing

While there is a growing interdependence of U.S. biopharmaceutical industries on international collaboration and resources, there have also been efforts made by the executive branch to increase domestic reliance on biotechnology and biomanufacturing processes.³⁴ One major effort to increase domestic biotechnology and biomanufacturing resources was a Biden 2022 Executive Order that launched the National Biotechnology and Biomanufacturing Initiative.³⁵ This order was intended to advance government investment significantly in biotechnology and biomanufacturing areas such as health, climate change, agriculture, supply chain resilience, etc.³⁶ The Office of Science and Technology ("OTSP") has also been working with other executive agencies, and co-authored a report with the U.S. Department of Agriculture

²⁷ Tan & Yang, *supra* note 15.

²⁸ Matej Mikulic, *Market Share of Leading 10 National Pharmaceutical Markets Worldwide in 2023*, STATISTA (Sept. 17, 2024), <https://www.statista.com/statistics/245473/market-share-of-the-leading-10-global-pharmaceutical-markets/>.

²⁹ *Biopharmaceuticals Market Size, Growth & Business Strategies*, TOWARDS HEALTHCARE (Jan. 29, 2025), <https://www.towardshealthcare.com/insights/biopharmaceuticals-market-is-rising-rapidly>; Jules Adam, *The Top-Performing Countries in Biotechnology (According to the OECD)*, LABIOTECHNOLOGY (Feb. 12, 2024), <https://www.labiotech.eu/best-biotech/top-biotech-countries/>.

³⁰ *Biopharmaceuticals Market Size, Growth & Business Strategies*, *supra* note 30; Adam, *supra* note 30.

³¹ The majority of which are American. See Evelien Moorken, Nicolas Meuwissen, Isabelle Huys, Paul Declerck, Arnold G. Vulto & Steven Simoens, *The Market of Biopharmaceutical Medicines: A Snapshot of a Diverse Industrial Landscape*, 8 FRONTIERS IN PHARMACOLOGY 1, 3-8 (2017).

³² *Id.*

³³ *See id.*

³⁴ *Bioeconomy*, USDA, <https://www.usda.gov/farming-and-ranching/plants-and-crops/biotechnology/bioeconomy> (last visited June 9, 2025).

³⁵ *Id.*

³⁶ *Id.*

(“USDA”) that outlines a vision for biotechnology and biomanufacturing in the United States.³⁷

The Trump administration may initiate substantial growth in domestic biotechnology and biomanufacturing.³⁸ President Trump’s first administration revolved heavily around an “America First” mindset.³⁹ In his first term, President Trump oversaw significant efforts to shorten the Federal Drug Administration’s (“FDA”) approval process, which led to a massive increase in novel drug approvals.⁴⁰ Currently, however, there seems to be no new investments in domestic biotechnology or biomanufacturing efforts planned for the immediate future.⁴¹

C. *The History of the BIOSECURE Act and Potential Reforms*

The growing interdependence of U.S. biopharmaceutical industries on international collaboration and resources has created concerns regarding national security and ethics.⁴² These concerns center around the fear that Chinese biotechnology companies, and other companies based in territories deemed “foreign adversaries,” could be compelled by their government to give up private American health data which could be weaponized against the United States.⁴³ Concerns over Chinese control of its companies are not new in Congress.⁴⁴ In early 2024, the Select Committee on the Chinese Communist Party released a report titled “How American Venture Capital Fuels the PRC Military and Human Rights Abuses.”⁴⁵ Though this

³⁷ See *Fact Sheet: President Biden to Launch a National Biotechnology and Biomanufacturing Initiative*, THE WHITE HOUSE (Sept. 12, 2022), <https://bidenwhitehouse.archives.gov/briefing-room/statements-releases/2022/09/12/fact-sheet-president-biden-to-launch-a-national-biotechnology-and-biomanufacturing-initiative>.

However, these initiatives may no longer exist under the current Trump administration. See *id.* Biden’s Executive Order has been archived on the White House’s website, and the link to the OTSP and USDA’s article is no longer valid. *Bioeconomy*, *supra* note 35.

³⁸ See *Trump Administration’s Impact on FDA Regulations: 5 Key Changes for Pharma & Biotechnology in 2025*, DLRC (Jan. 28, 2025), <https://www.dlrcgroup.com/trump-administrations-impacts-on-fda-regulations-5-key-changes-for-pharma-biotech-in-2025/>.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ See Maggie Fick & Bhanvi Satija, *Trump Health Policy Uncertainty Sends Biotechnology Sector into Deeper Slump*, REUTERS (Apr. 14, 2025, 10:53 AM), <https://www.reuters.com/business/healthcare-pharmaceuticals/trump-health-policy-uncertainty-sends-biotech-sector-into-deeper-slump-2025-04-14/>.

⁴² David M. McIntosh, Arthur C. Mok, & Geoffrey Lin, *Senate Committee Votes to Send the BIOSECURE Act to the Senate Floor*, ROPES & GRAY (Mar. 7, 2024), <https://www.ropesgray.com/en/insights/alerts/2024/03/senate-committee-votes-to-send-the-biosecure-act-to-the-senate-floor>.

⁴³ *Id.*

⁴⁴ See H.R. SELECT COMMITTEE ON THE STRAT. COMP. BETWEEN THE U.S. AND THE CCP., Y 4.2:C 44/C 17, CCP’S INVESTORS: HOW AMERICAN VENTURE CAPITAL FUELS THE PRC MILITARY AND HUMAN RIGHTS ABUSES (2024).

⁴⁵ *Id.*

report is not focused on the biopharmaceutical industry specifically, the problems it highlights are very similar to the reasons motivating the BIOSECURE Act.⁴⁶ This report reflects that many politicians are concerned about the potentially unethical nature of China’s clinical trials and the possibility of China stealing American data for militaristic uses.⁴⁷

The BIOSECURE Act was introduced by the House of Representatives to remedy these national security concerns by severing ties with biotechnology companies of concern.⁴⁸ While the five named companies are automatically classified as biotechnology companies of concern, the BIOSECURE Act also allows for the expansion of the classification list on the discretion of the Office of Management and Budget (“OMB”).⁴⁹

The BIOSECURE Act proposed by the House of Representatives mostly aligns with the original 2023 bill proposed by the Senate.⁵⁰ However, some of the most notable differences between the Senate bill and the House bill are the House’s inclusion of the safe harbor clause and a time limit on a proposed grandfathering clause.⁵¹ While the Senate bill includes a general grandfathering clause that would allow any previous contracts and services with biotechnology companies of concern before the BIOSECURE Act to continue, the House’s proposed BIOSECURE Act only allows for the continued contracts to be grandfathered for an eight-year period.⁵² Under the House’s proposed bill, companies will have to completely disassociate from biotechnology companies of concern by 2032.⁵³ The House’s version of the bill also includes a Safe Harbor Clause, which allows the U.S. government to work with biotechnology equipment or services that were affiliated with biotechnology companies of concern, as long as they are no longer owned by biotechnology companies of concern.⁵⁴

III. ANALYSIS

A. The Impact of Losing Chinese Biotechnology Companies

One of the most concerning impacts of the BIOSECURE Act for the biopharmaceutical industry is the naming of WuXi AppTec and WuXi Biologics as

⁴⁶ *Id.*

⁴⁷ McIntosh, Mok, & Lin, *supra* note 45.

⁴⁸ *Id.*

⁴⁹ BIOSECURE Act, H.R. 8333, 118th Cong. (2023–2024).

⁵⁰ See *BIOSECURE Act: Industry Closely Following in the Lame Duck*, FOLEY HOAG (Nov. 20, 2024), <https://foleyhoag.com/news-and-insights/publications/alerts-and-updates/2024/november/biosecure-act-industry-closely-following-in-the-lame-duck/>.

⁵¹ McIntosh, Mok, & Lin, *supra* note 45.

⁵² BIOSECURE Act, H.R. 8333, 118th Cong. (2023–2024).

⁵³ *Id.*

⁵⁴ *Id.*

automatic biotechnology companies of concern.⁵⁵ Eli Lilly collaborated with WuXi AppTec, one of the named biotechnology companies of concern to produce some of its ingredients in its GLP-1 obesity medications, and GSK entered in a licensing deal with WuXi Biologics in 2023 for bi-and-multi-specific T-cell engager antibodies WuXi developed to help fight cancer.⁵⁶ Without Wuxi, these medications may not be able to be produced.⁵⁷ The biggest impact of losing WuXi is not the loss of WuXi’s specific biotechnology services, but the loss of its contracting services.⁵⁸ WuXi AppTec is one of the largest global providers of contract development and manufacturing (“CDMO”), and there is heavy international reliance on the bioproducts it can supply to biopharmaceutical companies.⁵⁹ WuXi has a major presence in the U.S. biopharmaceutical industry, contributing in the creation of several drugs in the United States.⁶⁰ WuXi is also deeply intertwined with the American markets.⁶¹ WuXi AppTec and WuXi Biologics combined made around eight billion dollars of sales in 2023, in which more than half the profits came from the U.S. market.⁶²

Some biopharmaceutical companies that would be impacted because of WuXi’s inclusion in the BIOSECURE Act include Amicus, Eli Lilly, Sypre Therapeutics, Vir Biotechnology, Fibrogen, AgeX Therapeutics, and Structure Therapeutics, just to name a few.⁶³ Additionally, a portion of these companies will be disproportionately impacted by the loss of WuXi.⁶⁴ Amicus depends on WuXi Biologics as its sole supplier for a lab-made protein in the company’s treatment of Pompe disease.⁶⁵ WuXi STA, a subsidiary of WuXi AppTec, “is the sole provider of ingredients in a pipeline of cardiovascular drugs being developed by Structure Therapeutics.”⁶⁶

The loss of WuXi could have a severe negative impact on ongoing and developing clinical research.⁶⁷ Though there are other international suppliers companies can rely on, WuXi has earned its reputation as being the best and most diverse supplier

⁵⁵ Strom & Kros, *supra* note 14.

⁵⁶ Amy Baxter, *Biopharma Prepares to Pivot from China as Biosecure Act Advances*, PHARMAVOICE (Sept. 16, 2024), <https://www.pharmavoices.com/news/biopharma-china-biosecure-act-wuxi/727018/>.

⁵⁷ See Jared Whitlock, *Wuxi Became a Critical Partner to Biopharma Biopharma Companies. They’re Not Ready If the U.S. Cracks Down*, ENDPOINT NEWS (Mar. 13, 2024, 8:13 AM), <https://endpts.com/wuxi-became-a-critical-partner-to-biopharma-companies-theyre-not-ready-if-the-us-cracks-down/>.

⁵⁸ *Id.*

⁵⁹ Strom & Kros, *supra* note 14.

⁶⁰ *The Biosecure Act and Its Impact on Pharma: What You Need to Know*, LANGHAM LOGISTICS (Aug. 26, 2024), <https://www.elangham.com/2024/08/26/the-biosecure-act-and-its-impact-on-pharma-what-you-need-to-know/>.

⁶¹ Whitlock, *supra* note 61.

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

internationally.⁶⁸ Additionally, many other suppliers may not be able to supply the specific proteins or other complex products.⁶⁹ Even if biopharmaceutical industries are able to find new suppliers, the switch would take time, disrupting the supply of many lifesaving medications and potentially ruining emerging clinical studies.⁷⁰

B. Concerns Over the Language of the Prohibition on Grant and Loan Funds Clause

The BIOSECURE Act will also impact more than just federal government services and employees.⁷¹ The BIOSECURE Act prohibits federal funding to companies that use biotechnology equipment or services from biotechnology companies of concern.⁷² The distinction between the general clause and the prohibition on loan and grant funds is vital. The general clause only prohibits executive agencies from getting into contracts with companies who know or have reason to believe that they will use equipment or services from biotechnology companies of concern *in performance of the contract*.⁷³ The prohibition on loans and funding explicitly lacks that language and instead will prohibit federal loans and funding for companies that are contracting with biotechnology companies *in general*.⁷⁴

Many of the top biopharmaceutical companies in the U.S. rely heavily on federal funding for the research and development of drugs that will eventually be released into U.S. markets.⁷⁵ However, many important drugs are made through reliance on Chinese biotechnology companies.⁷⁶ Companies are considering turning to Indian suppliers to fill the gap; however, these companies rely heavily on Chinese companies for their active pharmaceutical ingredients.⁷⁷ New partnerships might also cause an even bigger delay in the supply chain, as companies will have to negotiate new vital supply agreements and find a new supplier as reputable as WuXi.⁷⁸ Biopharmaceutical industry, to be compliant with the BIOSECURE Act, will be forced to try and find new suppliers after years-long partnerships and familiarity with these biotechnology companies of concern.⁷⁹

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ See BIOSECURE Act, H.R. 8333, 118th Cong. (2023–2024).

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ Sujai Shivakumar, Tisyaketu Sirkar, & Jeffrey Depp, *Understanding the U.S. Biopharmaceutical Innovation Ecosystem*, CSIS (Aug. 15, 2024), <https://www.csis.org/analysis/understanding-us-biopharmaceutical-innovation-ecosystem>.

⁷⁶ Whitlock, *supra* note 61.

⁷⁷ HEALTH-ISAC, IMPACTS OF THE BIOSECURE ACT ON THE GLOBAL BIOTECH INDUSTRY, (Nov. 5, 2024), https://health-isac.org/wp-content/uploads/11.4.24_WP_ImpactsoftheBIOSECUREActontheGlobalBioTechIndustry.pdf.

⁷⁸ *Id.*

⁷⁹ *Id.*

C. Potential Issues Regarding Classifying Biotechnology Company of Concern

The way the BIOSECURE Act classifies biotechnology companies of concern means both U.S. biopharmaceutical and foreign biotechnology companies will get blindsided.⁸⁰ The BIOSECURE Act has only listed five major Chinese biotechnology companies as being classified as a biotechnology company of concern.⁸¹ However, more entities will be released in a list that is decided by the OMB based on a list provided by the Secretary of Defense in coordination with other pertinent executive offices.⁸²

The selection criteria and inclusion of new biotechnology companies of concern is concerning. First, the definition of foreign adversary is defined under 10 U.S.C. § 4872 (d)(2) as “the Democratic People’s Republic of North Korea, the People’s Republic of China, the Russian Federation, and the Islamic Republic of Iran.”⁸³ But this statute can be modified as political alliances shift, meaning that new countries can potentially be added to the BIOSECURE Act.⁸⁴ This uncertainty may cause unpredictable shifts in the biotechnology and biopharmaceutical industries.

Second, the OMB typically does not manage processes laid out in the BIOSECURE Act, such as the selection of biotechnology companies as potential national security threats.⁸⁵ The lack of OMB’s expertise in these areas may not be too damaging because the OMB chooses what is considered a biotechnology company of concern based on a list provided by other, better suited executive offices such as the Departments of Health and Human Services and Homeland Security.⁸⁶ However, this means that other departments, other the Department of Defense, may be able to influence OMB’s decision making, and it is unclear which ones may have the greatest influence.⁸⁷ This uncertainty could create a lack of accountability regarding which agency is actually classifying biotechnology companies of concern, and allows non-elected officials with unknown motives to assert a greater influence over the classification process.⁸⁸

Further, another potential issue with the classification of biotechnology companies of concern is the lack of advance notice to both biotechnology companies and the biopharmaceutical industry itself.⁸⁹ If a company is notified that they are a biotechnology company of concern, they have within ninety days of the receipt of notice to submit any information or arguments that will help them oppose the

⁸⁰ See Strom & Kros, *supra* note 14.

⁸¹ BIOSECURE Act, H.R. 8333, 118th Cong. (2023–2024).

⁸² *Id.*

⁸³ 10 U.S.C. § 4872 (d)(2).

⁸⁴ See *id.*

⁸⁵ Strom & Kros, *supra* note 14.

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ See *id.*

⁸⁹ See BIOSECURE Act, H.R. 8333, 118th Cong. (2023–2024).

designation.⁹⁰ If the company opposes the designation, then any knowledge that they are a biotechnology company of concern only gets released after the OMB has reviewed all information and issues a final determination that the company shall remain a listed biotechnology company of concern.⁹¹ However, the BIOSECURE Act gives no timeline to how long or rigorous the OMB's evaluation of these objections is, nor any specifications about the process or information biotechnology companies should submit.⁹² The lack of specifications means that companies that are appealing their status as a biotechnology company of concern would have no knowledge on whether they can legally work with American companies for an undetermined period of time.⁹³ The BIOSECURE Act also does not contain language about notifying businesses about potential biotechnology companies of concern, meaning that biopharmaceutical companies must remain vigilant about *all* Chinese, Russian, North Korean, and Iranian biotechnology companies, even if they may never be listed as a biotechnology company of concern.⁹⁴

The BIOSECURE Act essentially forces biopharmaceutical companies to try and cut off *all* ties with suppliers from these countries, or risk potentially being in collaboration with a biotechnology company of concern, which would cause unnecessary supply shortages, disrupted clinical trials, and drug price increases.⁹⁵

IV. RECOMMENDATIONS

While the BIOSECURE Act stems from very real ethical and national security concerns regarding foreign adversaries such as China, the impact of the current version of the BIOSECURE Act appears to be more detrimental to the American people than beneficial.⁹⁶ Although there is currently not much expectation that the BIOSECURE Act will get passed into law, the biotechnology and biopharmaceutical industries must remain vigilant.⁹⁷ The current Trump administration is still supportive of distancing relations with China. The situation with the Tik Tok ban shows that the Trump administration is not willing to accept Chinese companies, as the ban's reversal still hinges on Tik Tok not being owned by the Chinese company ByteDance.⁹⁸ Additionally, BIOSECURE Act is a bipartisan issue, meaning that if it ever *is* called up, it will most likely be passed.⁹⁹

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ Tan & Yang, *supra* note 15.

⁹⁶ *See generally supra* Part III.

⁹⁷ *See Biosecure Stalls, Will Not Become Law In 2024*, HOGAN LOVELLS, (Dec. 23, 2024), <https://www.hoganlovells.com/en/publications/biosecure-stalls-will-not-become-law-in-2024>.

⁹⁸ Allyn, *supra* note 1

⁹⁹ *Id.*

However, if passed as it currently is, the BIOSECURE Act will be detrimental to the pharmaceutical industry.¹⁰⁰ The need for the biopharmaceutical industry to cut off all Chinese connections, especially with WuXi, and find new suppliers of their main drugs and therapies by 2032 would cause massive supply shortages and distribution issues.¹⁰¹ Additionally, there is no guarantee that other biotechnology companies will exist that could replace the gap WuXi will leave in supplying specific complex proteins by 2032, when the grace period of the BIOSECURE Act is officially over.¹⁰²

If Congress wants to be able to mitigate national security threats without the expense of the American population, there are a number of options they should implement. First, there needs to be active investment into domestic biotechnology and biomanufacturing resources for the health industry.¹⁰³ To fix American biopharma's dependence on international biotechnology companies, we need to be able to create a reliance on American biotechnology companies instead.¹⁰⁴

However, creating a strong foundation of domestic biotechnology requires a lot of time. Thus, some of the BIOSECURE Act's provisions should be amended so they are more forgiving to current partnerships to allow the biopharmaceutical industry more time and stability.¹⁰⁵ One beneficial amendment would be to incorporate the Senate bill's grandfather clause.¹⁰⁶ Instead of only having an eight-year period for the biopharmaceutical companies to somehow find a way to resupply all their major drugs, all their previous contract deals will be grandfathered in, stabilizing the biopharmaceutical industry until domestic American biotechnology companies exist as a viable alternative solution.¹⁰⁷ Additionally, the language in the Prohibition of Loan and Grant Funding clause should be altered to mirror the scope of the General clause (2)(B).¹⁰⁸ This would mean that biopharmaceutical companies could still work with biotechnology companies of concern for their general patented drugs not meant for government contracts, without losing vital federal funding.¹⁰⁹

V. CONCLUSION

Overall, the BIOSECURE Act may be necessary for our nation's health industries to function without national security, privacy, and ethical concerns that arise from working with biotechnology companies potentially susceptible to working for foreign adversaries. However, before we can implement the BIOSECURE Act we need a

¹⁰⁰ *The Biosecure Act and Its Impact on Pharma: What You Need to Know*, *supra* note 64.

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ See discussion *supra* Section III.A.

¹⁰⁴ See *id.*

¹⁰⁵ *BIOSECURE Act: Industry Closely Following in the Lame Duck*, *supra* note 53.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ See BIOSECURE Act, H.R. 8333, 118th Cong. (2023-2024).

¹⁰⁹ See *id.*; Shivakumar, Sirkar, & Depp, *supra* note 79.

stronger domestic biotechnology foundation, which requires revision to the BIOSECURE Act to create more stability within the biotechnology and biopharmaceutical industry to hopefully reduce the impact on drug supplies and therapies in the U.S. while American biotechnology industries develop.