

BioSecure Insights: Economic Implications

Evaluating the Economic Impact of the BioSecure Act: A Critique of the Congressional Budget Office (CBO) Cost Estimate Analysis

April 19, 2024

- Fiscal Forecast Challenge: Our analysis suggests potential underestimations by the CBO, predicting higher government expenditure than anticipated.
- **Call for Comprehensive Analysis**: Beyond immediate fiscal impacts, the BioSecure Act's broader economic and societal externalities (i.e., benefits of R&D), demand a more inclusive evaluation.
- **Data-Driven Insights**: Historical parallels, like the ACA's impact, underscore the need for empirical evidence in forecasting the BioSecure Act's implications.
- Holistic Policy Approach: Recommendations for scenario analysis and modeling of externalities aim to enhance policy decision-making for economic and national security balance.

The *BioSecure Act (S. 3558)* (the Act) represents a pivotal legislative¹ effort with potential economic and strategic consequences for the U.S. biotechnology sector, particularly concerning market competition and access. This addendum to the *"Policy Brief: Navigating the BioSecure Act: A Multidimensional Analysis,"*² offers a respectful critical analysis of certain economic principles, emphasizing the inherent uncertainties and broader economic ramifications as projected in the Cost Estimates released by the Congressional Budget Office (CBO)³ on April 17, 2024. The Cost Estimate was "ordered by the Senate Committee on Homeland Security and Governmental Affairs on March 6, 2024"^{4,5} during a committee meeting. This addendum also provides an analysis examining potential market failures^a and externalities that could arise, specifically disruptions in research and development (R&D) that are vital for the US Government, societal, and business advancements. For additional insights on the BioSecure Act; *A Multidimensional Analysis*.

Economic Theories and Market Dynamics

The BioSecure Act's restrictive measures on biotechnology firms, particularly those from adversarial nations, are expected to considerably reduce the pool of market participants in the U.S.⁶ This reduction is likely to lead to diminished market competition. Classical economic theory posits that reduced competition often correlates with higher prices, as fewer firms mean less competitive pressure to keep prices low.^{7,8} This scenario could significantly impact consumers and businesses dependent on biotechnological products and services, given the sector's high price elasticity of demand (more on this below). Any price increase could disproportionately restrict access and stifle innovation in fields where alternatives are scant or nonexistent.

^a Market failure is defined as a situation in which an unregulated competitive market is inefficient because prices fail to provide proper signals to consumers and producers. Market failure occurs when externalities arise (Pindyck, R. et. al, at pg. 324).

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Economic Insights from the Proposed Improving Contracting Outcomes Act of 2024

While the *Improving Contracting Outcomes Act of 2024*° (*S. 4055*) has recently been introduced to Congress and is still undergoing its legislative journey, the principles it advocates could have significant utility in evaluating future market dynamics, pricing structures, and the potential effects of government-imposed bans. The *Improving Contracting Outcomes Act of 2024*¹⁰ marks a significant stride towards refining federal procurement by advocating for robust, outcome-oriented metrics.¹¹ This legislative direction could beneficially influence the Congressional Budget Office's (CBO) approach to economic evaluations, particularly the Cost Estimate Analysis of the *BioSecure Act*, as it is unclear what approach the CBO deployed. Additionally, integrating a transparent and comprehensive analysis framework that accounts for *externalities^b and market shifts* due to regulatory actions could enhance predictive accuracy and policy effectiveness (*The Improving Contracting Outcomes Act* currently does not have any provisions signaling evaluations of externalities). For instance, incorporating metrics that measure impacts on prices, supply, demand, and overall market dynamics alongside traditional fiscal outcomes, would provide a more nuanced understanding of legislative impacts. This broader approach would not only align with best practices in business management but also bolster governmental accountability and strategic decision-making, ensuring taxpayer funds are leveraged for optimal results.

Uncertainty and Hedging in Economic Outcomes

The legislative language that CBO used in its Cost Estimate suggests substantial uncertainty,¹² predominantly using hedging to moderate potential adverse economic impacts. This cautious approach, prudent for managing uncertainty and ambiguity inherent in policymaking, complicates economic analysis and future planning. The CBO's assessment acknowledges this uncertainty, stating that "the budgetary effects could be significantly greater or less than CBO's estimate"¹³ due to potential shifts in the price and availability of services from banned and affected companies. This uncertainty underlines a key issue: although substitutions for the banned entities may be feasible, the economic impact could be significant if these substitutes are more expensive or less available.

Economic Implications of Reduced Competition

The BioSecure Act effectively narrows the U.S. market to fewer domestic players by imposing stringent restrictions on biotechnology companies linked to foreign adversaries. This policy, intended to enhance national security, might inadvertently constrict certain market areas. The biotechnology sector, characterized by advanced technologies and specialized knowledge, typically features limited substitutes. This scarcity of alternatives intensifies the impact of reduced competition. Domestic companies might have diminished incentives to innovate or reduce prices when the market limits foreign competitors, who often provide lower-cost or uniquely differentiated products. Furthermore, if these foreign entities previously offered more cost-effective or unique products not fully replicated domestically, their absence could limit consumer choices and compel government agencies and healthcare providers to opt for more expensive or less effective alternatives. These implications may impact prices and government spending.

Impact on Prices and Government Spending

The *BioSecure Act's* implications for biotechnology may be profound, particularly due to the sector's significant contribution to healthcare and research budgets. Should the *BioSecure Act* lead to increased prices from diminished competition and limited substitution, US Government agencies and research institutions—primary consumers of biotechnological products—could face escalating costs. Given the sector's extensive involvement

^b Externalities are defined as actions by either a producer or a consumer that affect other producers or consumers but are not accounted for in the market price (Pindyck, R. et al., at pg. 662). Externalities may range in scope and depth, leading to varying levels of impact.



in federal contracts and government-funded programs, these higher costs are likely to be absorbed by the government, potentially inflating public expenditure. This might necessitate the reallocation of essential budgetary resources.

The Congressional Budget Office (CBO) projects that implementing the *BioSecure Act* will cost under \$500,000 over five years (2024-2029), presuming that federal agencies can find similar substitutes for banned biotechnological goods and services at equivalent costs. However, our limited simulation and statistical analyses of 1,487 publicly¹⁴ available data on government contracts^c reveal a different narrative: a marginal decrease in contract^d volume (-0.04%) coupled with a slight uptick in average contract price^e (+0.03%), equating to an average increase of **\$119.21** per contract. These observations project an additional government expenditure of approximately **\$386,350** or **(\$886,350 total)** over the same period, compared to \$500,000 projected, assuming a consistent number of contracts annually. This discrepancy highlights potential underestimations by the CBO regarding the economic effects of reduced market competition and the associated price increases. For process methodology, please refer to the Appendix.

Potential Market Failures, Externalities in the Context of the CBO Analysis

The Congressional Budget Office's assessment of the *BioSecure Act* acknowledges inherent uncertainties in the economic outcomes of the *BioSecure Act*. However, this may not fully capture the broader economic and societal externalities, particularly those related to disruptions in research and development (R&D) within the biotechnology sector. Biotechnology is integral to the US Government and societal advancement through its contributions to healthcare, agriculture, and environmental sustainability. The restrictive measures imposed by the BioSecure Act could lead to significant reductions in collaborative research efforts, which are vital for innovation and the continuous improvement of societal welfare. The current CBO's focus on budgetary impacts may overlook these critical externalities:

- 1. **Slower Pace of Innovation**: The *BioSecure Act* could result in a deceleration of the innovation cycle within biotech, as reduced competition and fewer market participants might decrease the incentive for rapid development and cross-border collaboration. This slowdown could delay the introduction of breakthrough technologies and medical treatments crucial for public health and agricultural productivity.
- 2. **Reduced Societal Benefits**: By potentially increasing the costs of biotechnological products and services (as noted by the minimal increase in contract prices and projected government expenditure), the *BioSecure Act* may make it economically infeasible for some research institutions and healthcare providers to access the latest biotechnological advancements. This restriction could lead to a decrease in the overall quality of health care and food security, particularly affecting low-income and vulnerable populations.
- 3. Net Welfare Loss: The combination of slowed innovation and reduced access to biotechnological advancements represents a significant external cost not captured in direct fiscal analyses available to the public. This scenario could lead to a net welfare loss, where the societal costs of reduced biotechnological advancement outweigh any benefits derived from increased national security through restrictive measures.

^c Represent a sample size from a much larger dataset. Limited to NIH as a procuring agency for simplicity. The sample also includes "companies of concern" identified in the BioSecure Act 2024 (S.3558).

^d Potentially arising from fewer companies available to compete for contracts.

^e Potentially resulting from fewer alternatives (products and services) available.



Integrative Recommendations for Policy Makers

As we pivot to a future where biotechnological innovation is intertwined with national security, the Congressional Budget Office (CBO)'s economic analyses must evolve to capture the full spectrum of legislative consequences. The *BioSecure Act* serves as a prime case study of this necessity. While the CBO's focused methodology is honorable and respectable for its detailed budgetary scrutiny, it is a single facet for comprehensive policy analysis. To elevate the level of analysis to the intricate realities of economic and policy ecosystems, we recommend the following strategies:

- Adopting Scenario Analysis and Sensitivity Testing: To navigate the complexities of the biotechnology sector and the *BioSecure Act's* ripple effects, the CBO should implement scenario analysis and sensitivity testing. This dual approach allows for a panoramic view of potential fiscal impacts under a kaleidoscope of market conditions and regulatory shifts. For example, examining the act's effects amidst varying levels of global market access or domestic investment would illuminate a more diverse set of economic outcomes, enabling policymakers to anticipate and strategize with greater agility.
- Quantifying Externalities through Modeled Projections: The *BioSecure Act's* true economic footprint extends beyond immediate fiscal impacts, casting long shadows on market dynamics and societal welfare. By modeling projections that quantify these externalities, akin to the ripples created by the *Affordable Care Act* in the healthcare market, we can better understand the longer-term implications for innovation and public health. Observations of investment trends and the market's responsiveness to pass legislation provide a historical compass guiding us toward more empirical and all-encompassing policy assessments.

Conclusion

The *BioSecure Act*, while aimed at bolstering national security by regulating foreign involvement in the U.S. biotechnology industry, could inadvertently lead to critical externalities, reduced market competition, fewer available substitutes, and ultimately, higher prices. These potential outcomes pose significant economic challenges, influencing market dynamics and placing increased financial burdens on government agencies—and by extension, taxpayers. The intricate relationship between national security initiatives and economic consequences highlights the urgent need for careful policy formulation. It is essential that such legislation not only secures against external threats but also promotes the health and vibrancy of the biotechnology market. Future policy decisions must therefore meticulously consider both the security and economic ramifications to prevent inadvertently stifling the innovation that drives sector growth.

About the Author:

Aldo M. Martinez, with 14 years in management consulting and healthcare policy, including Big 4 firm experience at PwC. As Lumiere Health International's Co-Founder and CEO, he advises his clients to navigate challenges and shape their healthcare innovation strategies. His advisory roles during the COVID crisis and at firms like PwC, and his strategic initiatives at Bayer, highlight his leadership. Mr. Martinez holds MBA and MPA degrees from Harvard and completed a biopharma R&D residency at MIT. He also serves as the President-elect of the Harvard Latino Alumni Alliance and enjoys running and cooking, emphasizing a balanced lifestyle. He lives in New York City with his family.



Appendix: Methodology Report

Economic Impact Analysis of the BioSecure Act

This appendix outlines the methodology employed to quantify the direct and extended financial impacts of the *BioSecure Act* on government expenditure, particularly focusing on contracts linked to the biotechnology sector. Important: The data sample is open source. The analysis respects data privacy and confidentiality by not revealing sensitive information about the companies. The methodologies and assumptions are openly discussed for transparency.

Data Sources and Methodology:

In our methodology, we employed industry-standard, robust analytics capabilities to ensure precise and comprehensive data analysis. This approach utilizes advanced analytic platforms that leverage tools and state-of-the-art capabilities such as Python, Pandas, and Matplotlib, aligning with best practices for data manipulation and visualization in the contemporary analytics landscape.

- 1. **Government Contract Data Analysis**: Analyzed publicly available contracts from the past ten years to establish baseline market conditions and average costs.
- 2. **Impact Simulation of the Ban**: Identified contracts associated with potentially banned companies, recalculating the market dynamics post-ban to assess the impact on contract prices and volumes.
- 3. **Financial Impact Analysis**: Calculated the percentage change in average contract prices and determined the additional cost implications for government spending.

Observations:

- Initial analysis indicated a minimal decrease in contract volume (-0.04%) and a slight increase in average contract price (+0.03%), translating to an average increase of \$119.21 per contract.
- Long-term projections suggest an additional government expenditure of approximately \$386,350 or (\$886,350 total) over five years.
- This methodology highlights the fiscal implications of the BioSecure Act, emphasizing potential increases in government expenditure and the resultant fiscal burden on taxpayers.

Limitations & Assumptions:

- The CBO's potential use of more extensive and unique datasets and advanced technologies may produce different results, influenced by varying assumptions in their analysis.
- The analysis of 1,487 contracts is a representative sample from a larger dataset, providing limited insights into government contracting trends to understand resource efficiency.
- The analysis assumes that the NIH is one of the largest purchasers of biotech products and services.
- The sum of \$886,350 over five years assumes a sustained average of 1,487 contracts annually.
- Complete data on total demand from government agencies is unavailable, highlighting access limitations to detailed internal data.

Recommendations for Further Research: Future studies should include a broader economic model to provide a comprehensive understanding of the full economic implications of regulatory changes, aiding policymakers, and stakeholders in better anticipating and managing these effects.



Notes (For full citations see Bibliography)

- ⁵ <u>https://www.cbo.gov/system/files/2024-04/s3558.pdf</u>
- ⁶ <u>https://www.ropesgray.com/en/insights/alerts/2024/03/the-biosecure-act-a-review-of-the-bill-responses-and-possible-repercussions</u>

⁷ <u>https://www.whitehouse.gov/cea/written-materials/2023/07/19/protecting-competition-through-updated-merger-guidelines/</u>

⁸ <u>https://www.mercatus.org/research/policy-briefs/antitrust-enforcement-2023-year-review-federal-trade-commission-and</u>

⁹ <u>https://www.congress.gov/bill/118th-congress/senate-bill/4055/Improvng Contracting Outcomes.</u>

¹⁰ Ibid.

¹² Ibid.

¹³ <u>https://www.cbo.gov/system/files/2024-04/s3558.pdf</u> at pg. 2

¹⁴ Dun & Bradstreet, Inc. (D&B), <u>https://www.fpds.gov/fpdsng_cms/index.php/en/</u>

* Citations and attributions have been provided truthfully and in good faith. This document leveraged certain

limited aspects of artificial intelligence technology for proofreading and formatting purposes.

¹ https://www.congress.gov/118/bills/s3558/BILLS-118s3558is.pdf

² <u>https://www.lumierehealth.org/thought-leadership/policy-brief-navigating-the-biosecure-act-a-multidimensional-analysis</u>

³ https://www.cbo.gov/system/files/2024-04/s3558.pdf

⁴ <u>https://www.congress.gov/bill/118th-congress/senate-bill/3558/all-actions.</u>

¹¹ Ibid. at Sec. 3. (b)



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- 6. Pindyck, Robert S., and Daniel L. Rubinfeld. *Microeconomics*. 8th ed. Boston: Pearson, 2013.
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