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The BIOSECURE Act

How companies can prepare

Presented by Tim Bergreen, Joy Sturm, Ajay Kuntamukkala, and Mike Druckman

Here with you today

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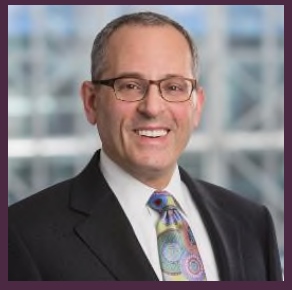

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Agenda

- Policy landscape - *Tim Bergreen*
- Summary of BIOSECURE proposals - *Joy Sturm*
- Potential trade sanctions - *Ajay Kuntamukkala*
- Impact on the pharmaceutical and biotechnology industry - *Mike Druckman*
- Key takeaways
- Q&A

Policy landscape

Presented by Tim Bergreen

What is driving Congress?

- "**China has been collecting genetic and health data from its entire population, bolstering the state's surveillance and security apparatus**, and its ability to try to monitor, manage, and control society in real-time. Beijing also has collected U.S. health and genomic data through its acquisitions and investments in U.S. companies, as well as cyber breaches."
  - U.S. Intelligence Community Annual Threat Assessment (Feb. 2023)
- **China seeks to become a world S&T superpower and to use this technological superiority for economic, political, and military gain.** Beijing is implementing a whole-of-government effort to boost indigenous innovation and promote self-reliance, and is prioritizing advanced power and energy, AI, **biotechnology**, quantum information science, and semiconductors. Beijing is trying to fast-track its S&T development through investments, intellectual property (IP) acquisition and theft, cyberoperations, talent recruitment, scientific and academic collaboration, and illicit procurements.
  - U.S. Intelligence Community Annual Threat Assessment (Feb. 2024)
- "**If the United States does not lead, others will, and we risk a future in which biotechnology undermines, rather than supports, U.S. national security**. The People's Republic of China intends to win the age of biology and is making significant investments and shrewd policy decisions with the intent to outpace the United States."
  - Policy Options to Promote Biotechnology in the Defense and Intelligence Communities (National Security Commission on Emerging Biotechnology March 2024)

Policy response - Congress

- Address threats to U.S. leadership in an identified “MADE IN CHINA 2025” / “Small Yard with High Fence” sector:
  - **Stop United States taxpayer dollars from flowing to foreign adversary biotech companies that have ties to the People’s Liberation Army (PLA);**
- Deprive PRC of U.S. person genomic/health data:
  - **Prevent U.S. taxpayers from buying biotech equipment from foreign adversaries that facilitate the transfer of United States person genetic data to a foreign adversary**.
- Where necessary or desirable: push China out of the U.S. biotech supply chain.
  - “Call-out” of specific companies in bill
  - Other efforts to push POTUS

What is Congress Considering? - The Two Bills

- S. 3558 was introduced in December 2023, by Sens. Colin Peters (D-MN), Bill Hagerty (R-TN) et al.
  - Considered in a markup by Committee on Homeland Security and Governmental Affairs on March 6, 2024
    - Committee vote was 11-1 in favor, with Sen. Rand Paul (R-KY - committee ranking member) the lone no vote.
- "The BIOSECURE Act" was introduced on January 25, 2024, by Reps. Gallagher (R-WI), Krishnamoorthi (D-IL) et al.
  - A modified version of the BIOSECURE Act (H.R. 8333) was introduced last Friday afternoon by a bipartisan group of Members led by Rep. Brad Wenstrup (R-OH)
  - Bill aligns more with the Senate version. Includes phase-in. Importantly, no commercial contracting ban.
- Both bills prohibit executive agencies from:
  - Procuring or obtaining equipment or service from a biotechnology company of concern;
  - Entering into a contract or extending or renewing a contract with any entity that:
    - a) Uses equipment or services from a biotechnology company of concern or
    - (b) Enters into any contract that will require direct use of equipment or services from a biotechnology company of concern;
  - Providing loans or grants to any company barred from a government contract due to the use of equipment or services provided by a biotechnology of concern.

Legislative timeline

1/25/2024

H.R. 7085 – Original BIOSECURE Act introduced in House

5/2024

Introduction and markup of H.R. 8333 – revised BIOSECURE Act

12/2024

Possible inclusion in NDAA

December 2023 — **December 2024**

12/20/2023

S. 3558 introduced in the Senate by Senators Peters and Hagerty.

3/6/2024

Senate Committee on Homeland Security and Governmental Affairs voted 11-1 to report S. 3558 to the full Senate

6/2024

Possible House Passage of H.R. 7085

Gazing into the future

- The Senate bill will not be considered by the full Senate as a standalone bill.
- However, the House bill to be marked up on Wednesday in the House Oversight Committee will likely be voted on by the full House later this spring/summer.
- That will be the end of the bill as a standalone piece of legislation, but **supporters intend to try to add it to the National Defense Authorization Act (NDAA).**
- **We assess that the potential for success via the NDAA is substantial, and the bill, in some form, could be law by the end of the year.**
- The NDAA will likely be finalized in the legislative session following the November U.S. election. Because of the procedural hurdles in passing standalone bills, the defense bill is traditionally a vehicle for other bills that could not pass on their own.
- **Because this process will likely lie unfinished for several months before final action, NOW is the time to educate Congress about the potential consequences. Even good legislation, carefully drafted, has unintended effects.**
- Both chambers/both parties say they are hearing **nothing about PATIENTS, COSTS, or PIPELINES**.
  - Original and revised legislation drafted quietly – likely LIMITED input
  - CBO Score shows a minimal cost to the USG –
- **THE BIG QUESTION: WHO WILL BEAR THE CONSEQUENCES? Patients? Innovation? Public Health?**
- **House sponsors revised – is it enough?**

Summary of BIOSECURE proposals

Presented by Joy Sturm

Topics

- Overview of proposed legislation
  - "Companies of concern"
  - Contracting restrictions
  - "Biotechnology equipment or services"
  - Potential for waiver and exceptions
  - Implementation/effective dates
- Government contract-related implications

BIOSECURE overview

- BIOSECURE comes in response to a perceived national security threat posed by Chinese "companies of concern" (CoCs) that are believed to have:
  - Access to U.S. genomic data, and
  - Ties to the Chinese military
- The purpose: to cut off the flow of U.S. genomic data to these CoCs and "root them out" of the U.S. supply chain by prohibiting their goods and services from being purchased by the U.S. government (USG)
- House/Senate bills include an initial list of CoCs, but more can be added
  - WuXi Apptech (+ updated House bill includes WuXi Biologics)
  - BGI, MGI, Complete Genomics
  - And parents, affiliates, successors

BIOSECURE overview: key restrictions

- Both bills would restrict the USG and its contractors from obtaining "biotechnology equipment or services" from CoCs.
  - Both reach USG contractors, grantees, *and* subcontractors
  - Both would prohibit arrangements with CoCs for biotechnology equipment or services that ultimately are provided to the USG ***in the "performance of [USG] contract[s]"***
  - Both apply ***prospectively*** and allow for ***"grandfathering"*** of existing contracts
  - An earlier version of the House bill would have rendered companies that simply do commercial business with CoCs ineligible to contract with the USG, even if the business was unrelated to any USG contract.
    - ***This broad commercial contracts ban has been removed.***

BIOSECURE overview: scope of coverage

- Can BIOSECURE impact companies that are ex-U.S.?
  - **Absolutely**.
  - All companies that do business with the USG in the biotechnology sector - regardless of their geographic location - can be impacted.
  - The restrictions reach companies that do business directly with the USG as well as those that do business indirectly by selling to private companies that contract with the USG.
- What "contracts" is BIOSECURE referring to?
  - United States Departments of Defense, Veterans Affairs, Health (including BARDA, NIH, Stockpile)
  - Federal hospitals/institutions, clinics, pharmacies
  - Contracts for finished goods as well as USG sponsored R&D contracts and grants
  - ***But not Medicare and Medicaid (for now):*** These Federal health programs generally do not purchase (procure) drugs and biotechnology directly, and instead serve as payers for products/services obtained through commercial channels. There has been talk about revising the House bill to encompass Medicare/Medicaid (a tall order).
- **The bottom line**: companies need to understand the scope of BIOSECURE to be able to assess whether and how it may impact them.

"Companies of Concern"

- Both the House (updated) and Senate bills restrict USG contracting with "***companies of concern,***" which include:
  - Beijing Genomic Institute (BGI), MGI, Complete Genomics, WuXi Apptec, and any ***subsidiary, parent, affiliate, or successor***, and
  - Updated House bill includes WuXi Biologics
- Both bills have an ongoing mechanism to add companies that are deemed to pose a "risk to national security" based on:
  - Joint research or sharing of multiomic/genetic data with
  - A foreign adversary/military establishment
- Both bills impose a notice requirement and afford certain due process prior to addition of a company to the list

Contracting restrictions

- The Senate bill and updated House bill would prohibit executive agencies from:
  - ***Procuring or obtaining*** *"*biotechnology equipment or service" that has been "***produced or provided"*** by a "company of concern"
  - ***Entering into a procurement contract*** with any company that:
    - **Uses** biotechnology equipment or services obtained from a CoC "***in the performance" of a USG contract***
    - **Enters into a contract with a business partner (subcontract):** for biotechnology equipment or services and the company knows (or has reason to believe) that the equipment/services ***are provided by a CoC*** and would be ***used in the performance*** of a USG contract.
      - This is meant to cover situations where biotechnology equipment or services are provided by a CoC ***further down the supply chain***, but ultimately in support of a USG contract.
- Both bills also:
  - Apply the restrictions to USG grants and loans, and
  - Apply the restrictions ***prospectively*** to agreements awarded after enactment and implementation of BIOSECURE

Contracting restrictions – grandfathering + "safe harbor"

- Grandfathering of existing USG contracts
  - Senate bill – grandfathering is open-ended
  - House (updated) bill:
    - For CoCs identified in the bill, existing USG contracts would be grandfathered for a period of up to ***7 years*** (through January 2032), and
    - For companies designated as CoCs subsequent to enactment of BIOSECURE, grandfathering would last for *5 years* after a company receives the CoC designation
- Grandfathering applies to ongoing contracts and priced options – not renewals/extensions
- New "safe harbor" for biotechnology equipment and services "formerly" but no longer are produced or provided by a CoC – that have been divested

"Biotechnology Equipment or Service"

- "Biotechnology equipment or service" is ***defined broadly*** to include:
  - Equipment (including genetic sequencers, mass spectrometers, and polymerase chain reaction machines) or any other instrument, apparatus, machine, device (or components or accessories for the foregoing) "designed for use in the "research, development, production, or analysis of biological materials" (including software, firmware, and digital components of such equipment)
  - Services for the "research, development, production, analysis, detection, or provision of information (including data storage and transmission) related to biological materials"
    - Includes consulting/support services related to use or implementation of such equipment
    - Includes disease detection, genealogical information, and related services
- ***Catchall provision allows*** Office of Management and Budget (OMB) (with Agency heads) to supplement this definition as OMB "determines appropriate."

Waivers and exceptions in both bills

Framework for obtaining a waiver:

- Authority to Grant Waiver: Agency heads can waive the restrictions on a ***case-by-case*** basis with OMB of approval and notification and justification to Congress
- Duration: A waiver may be granted for no more than ***one year***
- Extension: A waiver may be extended one time for an additional ***6 months***

Exceptions where the BIOSECURE restrictions do not apply:

- Activities relating to authorized U.S. intelligence activities
- Provision of health care services overseas for USG or contractor employees
- Acquisition, use, or distribution of human multiomic data that is ***commercially or publicly available***.

Implementation/effective dates

- **OMB guidance:**
  - OMB is tasked with issuing guidance on BIOSECURE within ***120 days*** of enactment
- **Federal Acquisition Regulation [FAR] implementation:**
  - The "FAR Council" must revise the regulations to implement BIOSECURE contracting prohibitions within ***one year*** after the OMB guidance is issued
- **Only once implementing FAR clauses are effective, will BIOSECURE apply to USG contracts - and *only to future contracts*:**
  - If BIOSECURE is enacted at end of 2024, then FAR clause implementation to new contracts likely would not take place before Q2 2026

Government contract-related implications

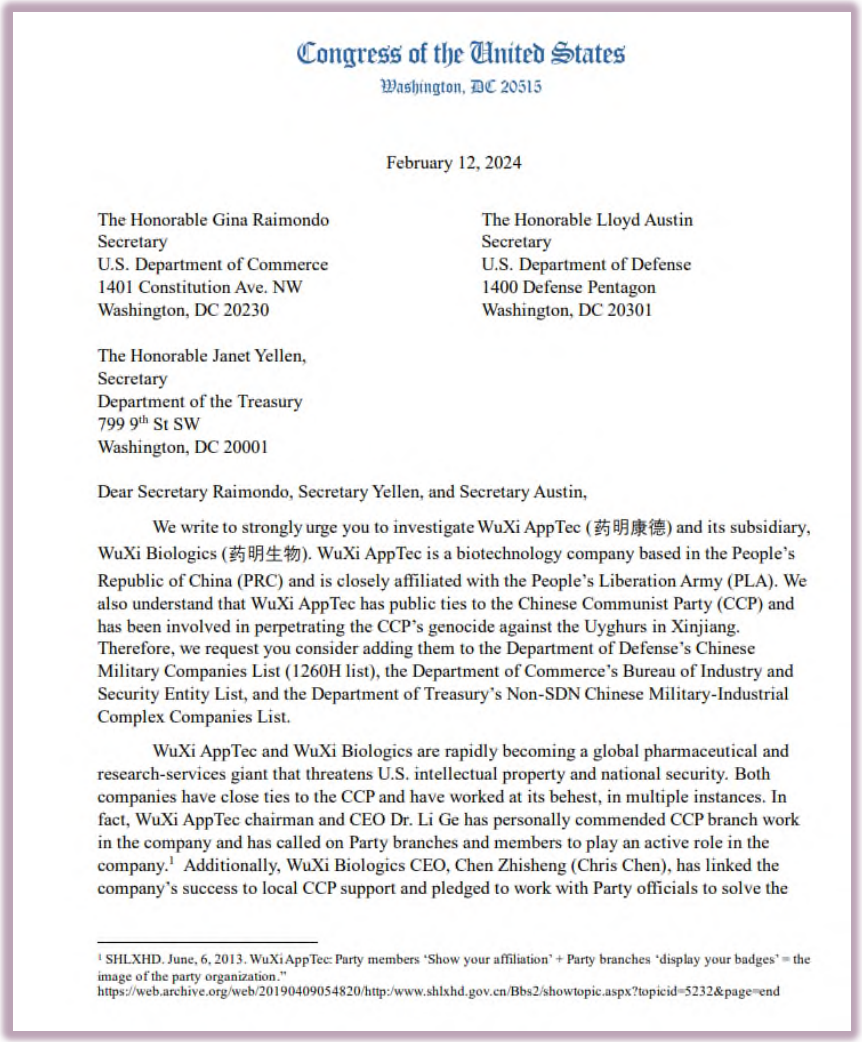
- Companies should consider the scope of what they supply to the USG under current and potential future contracts and whether covered "biotechnology equipment or services" provided by CoCs would (or could) be provided "in the performance" of a USG contract/grant.
  - For USG contracts or grants that require clinical research and development, obtaining services or equipment from a CoC that is needed in the performance of those services would be covered.
  - But, for contracts with the USG for finished goods such as medical equipment or biologics, research services performed by a CoC during product development likely would not be considered to be "in the performance of" the USG contract. On the other hand, ongoing manufacturing services that are required in order to supply product very well could be (risk of genomic data going to China).
- Consider timing of when the BIOSECURE restrictions might impact your company, taking into account the ***prospective nature*** of the restrictions and ***grandfathering*** of existing contracts
- Stay up-to-date on potential trade sanctions that may be applied to CoCs and other biotechnology companies - as ***certain sanctions would prohibit contractors from obtaining supplies or services from sanctioned companies regardless*** of whether BIOSECURE is enacted.

Potential trade sanctions

Presented by Ajay Kuntamukkala

Additional Congressional action

- On February 12, 2024, members of Congress sent a letter to the Departments of Commerce, Treasury, and Defense to request that WuXi AppTec and WuXi Biologics be added to the Department of Defense's Chinese Military Companies List, the Department of Commerce's Bureau of Industry and Security's Entity List, and the Department of Treasury's Non-SDN Chinese Military-Industrial Complex Companies List.
- The letter cited the companies' ties to the People's Liberation Army and the Chinese Communist Party.



Congress of the United States
Washington, DC 20515

February 12, 2024

The Honorable Gina Raimondo
Secretary
U.S. Department of Commerce
1401 Constitution Ave. NW
Washington, DC 20230

The Honorable Lloyd Austin
Secretary
U.S. Department of Defense
1400 Defense Pentagon
Washington, DC 20301

The Honorable Janet Yellen,
Secretary
Department of the Treasury
799 9th St SW
Washington, DC 20001

Dear Secretary Raimondo, Secretary Yellen, and Secretary Austin,

We write to strongly urge you to investigate WuXi AppTec (药明康德) and its subsidiary, WuXi Biologics (药明生物). WuXi AppTec is a biotechnology company based in the People's Republic of China (PRC) and is closely affiliated with the People's Liberation Army (PLA). We also understand that WuXi AppTec has public ties to the Chinese Communist Party (CCP) and has been involved in perpetrating the CCP's genocide against the Uyghurs in Xinjiang. Therefore, we request you consider adding them to the Department of Defense's Chinese Military Companies List (1260H list), the Department of Commerce's Bureau of Industry and Security Entity List, and the Department of Treasury's Non-SDN Chinese Military-Industrial Complex Companies List.

WuXi AppTec and WuXi Biologics are rapidly becoming a global pharmaceutical and research-services giant that threatens U.S. intellectual property and national security. Both companies have close ties to the CCP and have worked at its behest, in multiple instances. In fact, WuXi AppTec chairman and CEO Dr. Li Ge has personally commended CCP branch work in the company and has called on Party branches and members to play an active role in the company.[1] Additionally, WuXi Biologics CEO, Chen Zhisheng (Chris Chen), has linked the company's success to local CCP support and pledged to work with Party officials to solve the

[1] SHLXHD. June, 6, 2013. WuXi AppTec: Party members 'Show your affiliation' + Party branches 'display your badges' = the image of the party organization."
https://web.archive.org/web/20190409054820/http:/www.shlxhd.gov.cn/Bbs2/showtopic.aspx?topicid=5232&page=end

U.S. Restricted Party Lists

- The U.S. Government maintains several restricted party lists administered by the U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) and the U.S. Department of Commerce's Bureau of Industry and Security (BIS).
- The restrictions vary depending on the list, with some lists prohibiting all activity and other lists restricting certain activity.
- Restricted Party Lists include:
  - **OFAC's Specially Designated Nationals and Blocked Persons List (SDN List):** All transactions and dealing involving an SDN where there is a U.S. nexus (i.e., U.S. persons, U.S. dollars, and items subject to U.S. law) are prohibited.
  - **OFAC's Non-SDN Chinese Military-Industrial Complex Companies List (NS-CMIC LIST):** U.S. persons are prohibited from dealing in publicly traded securities of parties on the NS-CMIC List.
  - **BIS's Entity List:** Generally imposes a license requirement to export, reexport, or transfer all items subject to U.S. law to parties on the Entity List.
  - **BIS's Military End User List and Military-Intelligence End User List:** Items subject to U.S. law may require a license to these end users. The restrictions apply not just to specific parties listed but to any party that meets the definition of "military end user" or "military-intelligence end user."
  - **Department of Defense's Chinese Military Companies List:** does not impose any legal obligations (in the future DoD will be prohibited from directly or indirectly procuring items from parties on the list) but is a red flag to further review a company to determine whether it meets BIS's definition of "military end user" or "military-intelligence end user."

Potential Impact of Restricted Party Designations

What would designation mean?

- Adding Wuxi AppTec and WuXi Biologics to the Entity List would impose a BIS license requirement.
  - All items subject to U.S. law (regardless of whether U.S. persons or U.S. dollars are involved) that are sent to Wuxi AppTec or WuXi Biologics would require a license from BIS.
  - This license requirement applies even when Wuxi AppTech or WuXi Biologics is the purchaser or intermediary.
  - BIS maintains certain license exemptions but parties on the Entity List are not eligible.
  - BIS generally reviews license applications with a policy of denial.
- Inclusion on the SDN List would cut off the companies from the U.S. financial system and all transactions that directly or indirectly involve items subject to U.S. law, U.S. dollars, and U.S. persons would be prohibited.

Impact on the pharma/biotech industry

Presented by Mike Druckman

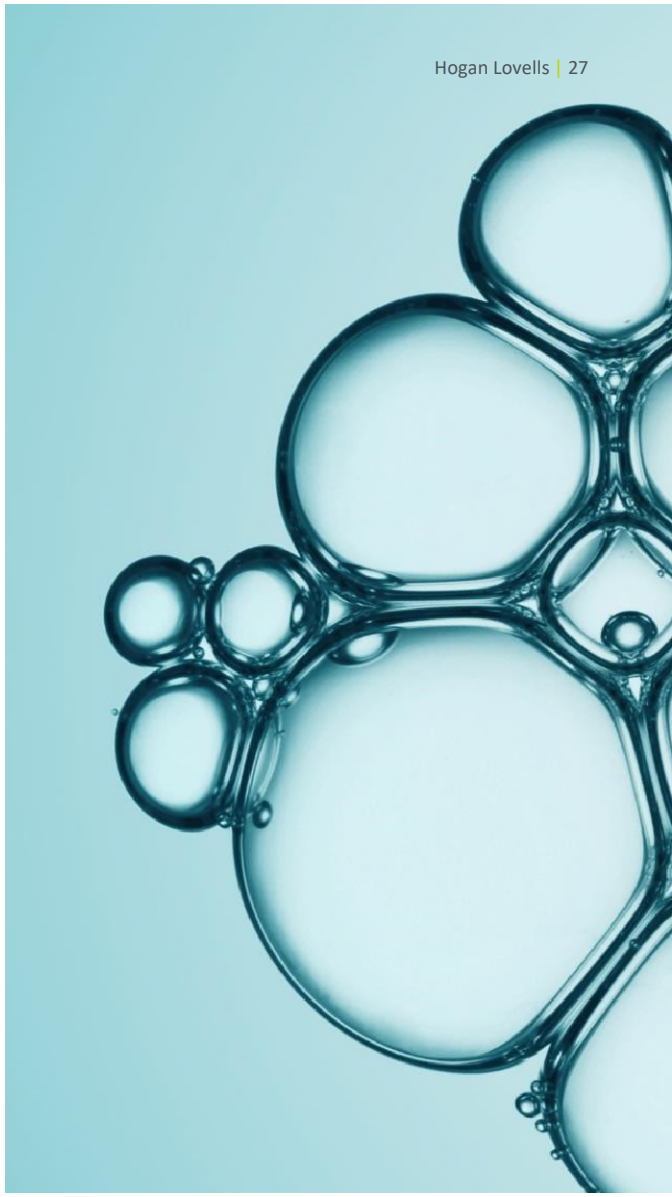
Impact on Industry in the U.S.

- Over 90% of surveyed biotech companies expect pipeline delays if legislation passes [1]
  - In an updated survey, 74% of surveyed biotechs reported contracts with Chinese CDMOs/CMOs for preclinical and clinical services [3]
  - Those biotechs estimated that it would take up to **6 years** to switch those services to other companies [3]
- 30% of surveyed biotechs reported contracts with Chinese CDMOs/CMOs for manufacturing [3]
  - They reported that it might take up to **8 years** to switch manufacturing of approved products to alternative companies [2,3]
- If passed into law, the Act could put U.S. companies at a global disadvantage[1]

[1] C. Simone Fishburn, Anti-China bills portend massive blow to biotech: BioCentury Survey, BioCentury (Mar. 21, 2024)

[2] Christina Jewett, U.S. Scrutiny of Chinese Company Could Disrupt U.S. Supply Chain for Key Drugs, The New York Times (Apr. 15, 2024)

[3] S. Usdin, BIO survey shows impacts of Biosecure Act, BioCentury (May 9, 2024)



Impact on Industry in the U.S. (Cont.) – Why such impact?

- "A company like WuXi Biologics provides a service that is difficult to get at the same price and timelines," according to a surveyed biotech [1]
  - More than half of surveyed companies said it would be extremely difficult to replace those services [1]
- WuXi Apptec's U.S. revenue is over $3.5 billion [1,2]
- WuXi Apptec and its subsidiary WuXi Biologics may have been involved in developing ¼ of all U.S. drugs[2]
- WuXi Apptec and WuXi Biologics make some or all of the main ingredients in multibillion dollar therapies for cancer, HIV, obesity and other diseases[2]
- Companies are beginning to seek alternative contract manufacturers now [1,2,3]
- 2/3 of surveyed companies said they are unlikely to sign a new contract with a China-based CDMO given uncertainty created by these bills. [1]

[1] C. Simone Fishburn, Anti-China bills portend massive blow to biotech: BioCentury Survey, BioCentury (Mar. 21, 2024)

[2] Christina Jewett, U.S. Scrutiny of Chinese Company Could Disrupt U.S. Supply Chain for Key Drugs, The New York Times (Apr. 15, 2024)

[3] Amber Tong, Novartis will change CRO relationships "over time" as Senate bill targeting Chinese companies looms, Endpoints News (April 23, 2024)

Alternative contract manufacturer considerations

- When choosing an alternative manufacturer, companies should:
  - Review the alternative manufacturer's inspection history
  - Assess the appropriateness and function of the alternative manufacturer's quality system
  - Compare the types of operations historically performed at the alternative manufacturer's facility to the operations associated with the change
    - *FDA recommends that a change in manufacturing site, even when the new manufacturing site is routinely subject to FDA inspection, be submitted as a prior approval supplement if the site does not have a satisfactory current Good Manufacturing Practice (cGMP) inspection for* ***the type of operation which will be required under the change***
  - Evaluate the quality and compliance culture at the alternative manufacturer's site
  - Analyze the alternative manufacturer's association with a foreign adversary

Consider timing for qualification and validation

- The process for qualifying a new contract manufacturer can include:
  - Site audit, including evaluation of existing current cGMP status
  - Evaluation of potential impact of the change on a product
    - FDA Guidance on Cell and Gene Therapy notes that some changes can fundamentally alter the product, resulting in a new product
  - Readying the new manufacturing facility to release commercial product will require validation studies, such as:
    - Analytical methodology validation
    - Process, cleaning, and data management systems validations
- Consider time for preparing for pre-approval inspections by regulatory authority
- Consider time needed to accomplish technology transfers
  - External technology transfers involve data transfers and intellectual property licensing
  - Internal technology transfers involve preparing equipment and systems for manufacturing, assessing standard operating procedures, and training staff
- Consider time needed to negotiate an adequate quality agreement, that sufficiently defines quality measures, sets out subcontracting considerations, and grants sponsor robust auditing rights

Prior FDA approval required

- Under FDA regulations, sponsors are required to report all changes to manufacturing specifications, and to **obtain prior agency approval** when making a change that has substantial potential to have adverse effect on product quality as it relates to safety and efficacy of product
- Moving to a new contract manufacturer often requires changes to:
  - Equipment
  - Facilities
  - Responsible personnel
- Sponsors should therefore evaluate whether the changes should be reported to FDA in a supplement to the approved application
  - Many will require a prior approval supplement (PAS) for drugs, or a PMA supplement or a new 510(K) for devices

Prolonged FDA review and approval time

- FDA has a goal for reviewing and acting on original PAS manufacturing supplements for drugs and biologics **within 4 months** of receipt of such applications
  - FDA will act on other manufacturing supplements within **6 months** of receipt
- However, this goal date can be further prolonged by:
  - Major amendments to the application during the review cycle which, can further delay approval by an additional 2 months
  - Inspection issues at the alternative manufacturer's facility
- For Class III medical devices, FDA review timelines for PMA supplements vary, between 30 and 180 days
- For cleared medical devices, changes that could affect safety and effectiveness require a new 510(K), which is a 90-day review

Key takeaways

So, now what?

- **Identify and review all agreements, including contracts, purchase orders, and MOUs with companies of concern (and their affiliates) + other labs, CMOs, CDMOs in China**
  - Assess the potential impact of BIOSECURE proposals and potential restricted party designations
- **Review current USG contracts, grants, subcontracts – consider existing and/or plans to enter into USG contracts in the future**
- **Consider potential exit strategies:**
  - Assess any existing termination clauses
  - Consider potential amendments to scope
- **Assess potential to pivot to make alternative plans with other labs – consider timing!!**
  - Timing of applicability of law
  - Timing to exit existing agreements and to move ahead with other labs
- **Consider whether your company may have an interest in trying to influence the BIOSECURE proposals**
  - Given how fast they are moving through Congress, the time to assess is now.

Questions?

Thank you!

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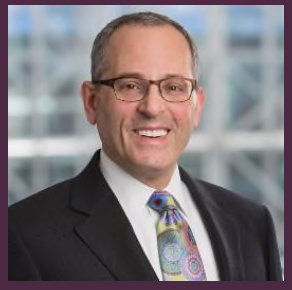

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